April 4, 2011

Health Headlines

CMS Releases Proposed ACO Rule – On Thursday, March 31, 2011, CMS released a copy of the Proposed Rule implementing the Shared Savings Program/Accountable Care Organization (ACO) provisions of the Affordable Care Act (Pub.L. 111-148 § 3022). Simultaneous with issuance of the Proposed Rule, CMS and OIG jointly published a notice requesting comments on proposed waivers of certain fraud and abuse laws for ACOs participating in the Shared Savings Program. In addition, the IRS issued a notice requesting comments as to whether existing guidance is sufficient to ensure that ACO participation by tax-exempt entities will not result in violation of the existing proscriptions against prohibited inurement or impermissible private benefit. Further information about the IRS notice and the joint CMS/OIG notice may be found below.

In its pre-publication form, the Proposed Rule runs over 400 pages. It describes an intensive and voluminous application process for ACOs seeking to participate in the Shared Savings Program. ACOs may include the following participants:

- group practices;
- networks of individual practices;
- partnerships/joint ventures between hospitals and physicians/mid-level providers ("ACO professionals");
- hospitals employing ACO professionals;
- other providers/suppliers recognized under the Social Security Act; and
- critical access hospitals.

Each ACO's participants must be proportionally represented on the ACO's governing body, and the governing body must also include at least one Medicare beneficiary who is being served by the ACO. The Proposed Rule encourages ACOs to include community service representatives on the governing body as well.

Under the Proposed Rule, an ACO may opt to participate in the Shared Savings Program under a "two-sided" model, which involves sharing of both gains and losses with the Medicare program. The other option is a "one-sided" model in which the ACO shares in savings to the Medicare program at a rate that is more modest than the one available under the two-sided model. CMS calculates the savings or loss by determining whether the estimated average per capita Medicare expenditures for ACO beneficiaries is below a benchmark established by CMS for each ACO.

The minimum period of participation in the Shared Savings Program is 3 years. If an ACO opts for the one-sided model, it must agree to participate in the two-sided model in the third year. A participant in the two-sided model must obtain a

surety bond or otherwise demonstrate that it has the financial wherewithal to repay any losses to the Medicare program. Further, in both models, the ACO's share in savings is subject to a 25% withhold to ensure repayment of any Medicare losses. A specific request for a Shared Savings payment must be submitted by the ACO, one which certifies to its compliance with program requirements and to the accuracy of any data submitted.

Each ACO must have a minimum of 5000 Medicare beneficiaries assigned. Assignment of Medicare fee-for-service beneficiaries to an ACO, as proposed, will take place at the ***end*** of a performance year, although CMS has specifically requested comments on this point. CMS will identify all Medicare beneficiaries who received a primary care service from an ACO professional, and any beneficiary who received a plurality of his or her primary care services (based on total charges) from the ACO professional will be assigned to the ACO in which the ACO professional participates. CMS points out that prospective assignment of Medicare beneficiaries would require a retrospective adjustment anyway, to account for beneficiaries who move out of the area, leave fee-for-service Medicare or receive care outside of the ACO. CMS also believes that ACOs who know their assigned beneficiaries in advance may not focus on improving care coordination for all Medicare patients in the practice.

The Proposed Rule includes comprehensive provisions on structural requirements for ACOs, on quality and other data that must be reported, and on information technology infrastructure. At least 50% of the ACO's primary care physicians must be meaningful users of certified EHR technology pursuant to the HITECH Act by the start of the second performance year. CMS will share certain Medicare claims data information, both aggregated and beneficiary-specific, if requested by an ACO and subject to compliance with HIPAA rules. The shared data will apply to the ACO's "expected assigned population," to help the ACO profile its population and better manage care. Aggregate data reports based on the most recent 12 months of data will be furnished at the start of the performance period. Beneficiary-specific claims information will be made available on a monthly basis.

To address antitrust concerns, ACOs with a greater than 50% share for any common service that two or more ACO participants furnish to patients from the same Primary Service Area must undergo an expedited anti-trust review. Those with a share that is greater than 30% but less than 50% may undergo an expedited anti-trust review or may opt to abide by restrictions that are deemed to alleviate any anti-trust concerns.

Under the Proposed Rule, ACOs are required to release certain information to the public, including:

- participating providers and suppliers;
- identification of participants in joint ventures between ACO professionals and hospitals;
- quality performance standard scores;
- shared savings and losses; and
- the proportion of shared savings distributed to participants, and used to support quality performance and the other ACO goals.

The Proposed Rule may be viewed by clicking **here**. King & Spalding will be offering a Healthcare Roundtable on the Proposed Rule on April 15, 2011, as discussed further below.

Reporter, *Nancy LeGros*, Houston, +1 713 751 3249, nlegros@kslaw.com.

U.S. Antitrust Enforcement Agencies Release Policy Statement Regarding ACOs – On March 31, 2011, the United States Department of Justice (DOJ) and Federal Trade Commission (FTC) released for public comment a joint Policy Statement regarding how the agencies will enforce the antitrust laws regarding Accountable Care Organizations (ACOs). The Policy Statement accompanies the release on the same day by CMS of its proposed regulations to cover ACOs participating in the Medicare Shared Savings Program. Comments are due by May 31, 2011.

The joint Policy Statement covers five areas: (1) the ACOs to which it will apply; (2) when the FTC and DOJ will apply a

"rule of reason" antitrust analyses to those ACOs; (3) an antitrust "safety zone" for ACOs with less than 30 percent market share and non-exclusive ACOs in rural counties; (4) a mandatory antitrust review process for ACOs with market share in excess of 50 percent; and (5) how the agencies will review proposed ACOs with market share between 30 and 50 percent.

In addition, the Policy Statement describes how the parties can obtain an "expedited review" by submitting certain types of information and documents to the reviewing agency at least 90 days before the last day that CMS has stated it will accept ACO application for the relevant calendar year. The agency will provide its opinion (i.e. that the ACO is permissible or that the agency will challenge the ACO) within 90 days of receiving all of the information from the parties.

The Policy Statement is the first major healthcare policy pronouncement from the antitrust enforcement agencies since the FTC/DOJ Competitor Collaboration Guidelines were issued in 2000 and reflects efforts by the DOJ to play a greater role in healthcare antitrust enforcement, as the FTC has historically been the primary agency involved in provider-related healthcare antitrust matters.

The FTC's press release regarding the Policy Statement is available by clicking **here**.

Reporter, *John Carroll*, Washington, D.C., +1 202 626 2993, jdcarroll@kslaw.com.

CMS/OIG Notice Regarding Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center – The Affordable Care Act authorizes the Secretary of HHS to waive certain fraud and abuse laws as necessary to carry out the provisions of the law regarding the Medicare Shared Savings Program. In addition, the Affordable Care Act authorizes the Secretary to waive these laws as necessary to carry out the provisions of the law regarding the testing of innovative delivery and payment models by the newly established Center for Medicare and Medicaid Innovation (CMI). With the release of the proposed ACO rule, CMS and OIG published a notice that describes certain proposed waivers that will relate to the ACO and CMI programs and solicits comments relating to additional or different waivers to implement these programs.

Waivers Applicable to the ACO Shared Savings Program. The Affordable Care Act authorizes a waiver of the provisions of the Stark Law (42 U.S.C. § 1395nn), the Anti-Kickback Statute (42 U.S.C. § 1320a-7b), and the Civil Money Penalties Law (42 U.S.C. § 1320a-7a), including that provision prohibiting a hospital's payment to a physician to reduce or limit care to a Medicare or Medicaid beneficiary (referred to in the notice as the "Gainsharing CMP"). With respect to the proposed exercise of its waiver authority relating to the ACO shared savings program, CMS/OIG noted the following:

- Participants in the Shared Savings Program will continue to receive Medicare fee for service payments, as well as be eligible to receive additional shared savings. Therefore, the fraud and abuse laws designed to safeguard the Medicare program and beneficiaries in the fee-for-service context continue to be relevant.

- No clear consensus emerged from public comments solicited to date regarding the nature and scope of waivers needed to implement the ACO program (the agencies acknowledged this could arise from the fact that the ACO rule had not yet been published when the waiver comments were solicited).

- No waivers are needed for arrangements that do not violate these laws or that fit within an existing Stark Law exception or Anti-Kickback safe harbor.

- The contemplated waivers as described in the notice do not pertain to any other federal or state law other than the sections cited in the Affordable Care Act, and "[a]ll financial arrangements not covered by a waiver would be required to comply with existing laws."

All of the proposed waivers relate to the ***distribution of shared savings*** received by an ACO from CMS pursuant to the Shared Savings Program. As a threshold qualification for any of the proposed waivers, ACOs would be required to hold an agreement with CMS to participate in the Shared Savings Program, and the participating ACO, ACO participants, and ACO providers/suppliers would be required to comply with that agreement, as well as the law creating the Shared Savings

Program and the regulations implementing the program (including transparency, reporting and monitoring requirements).

The waivers contemplated by CMS and OIG are as follows:

- The Secretary would waive the application of the Stark Law and the Anti-Kickback Statute to distributions of shared savings received by an ACO from CMS (1) to or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or (2) for activities necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program.
    - The Secretary would waive application of the Anti-Kickback Statute with respect to any financial relationship between or among the ACO, ACO participants and ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program that implicates the Stark Law and fully complies with an exception at 42 C.F.R. §§ 411.355 through 411.357 of the Stark rules (the exceptions for ownership interests and compensation relationships).
    - CMS and OIG do not intend to protect distributions of shared savings dollars to referring physicians outside the ACO unless those physicians are being compensated for activities necessary for and directly related to the ACO's participation in and operations under the program.
    - All other financial relationships (beyond distributions of shared savings) involving physicians or entities participating in the ACO, as well as other financial relationships outside the ACO, would need to meet an existing exception under the Stark Law, and an existing safe harbor under the Anti-Kickback Statute (or otherwise comply with the Anti-Kickback Statute).
- The Secretary would waive application of the Gainsharing CMP to –
    - Distributions of shared savings received by an ACO from CMS under the Shared Savings Program to ACO participants or ACO providers/supplier, if the payments are not made knowingly to induce the physician to reduce or limit medically necessary items or services; and
    - Any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program that implicates the Stark Law and fully complies with an exception at 42 C.F.R. §§ 411.355 through 411.357.
- The waivers would be limited in duration to the term of the ACO's agreement with CMS (although shared savings distributions earned under the CMS agreement could be distributed consistent with the waiver after the agreement expired).

Solicitation of Comments on Additional or Different Waivers. CMS and OIG note that they received "significant public input" suggesting that their waivers apply more broadly than the proposed waivers outlined in the notice. Therefore, in the notice they seek additional public comments on a number of different topics, urging such comments to address why any additional or different waivers would be necessary to carry out the provisions of the Shared Savings Program and why the financial relationship would not qualify for existing exceptions or safe harbors. In connection with any proposed waivers, the notice solicits public comment on the inclusion of standards relating to fair market value and commercial reasonableness as additional safeguards.

The specific topics outlined in the notice for additional public comment include whether it is necessary to waive the Stark Law, Anti-Kickback Statute or Gainsharing CMP for remuneration relating to –

- Establishment of the ACO, including investments, start-up expenses, and nonmonetary benefits;
- Financial relationships other than the distribution of shared savings among ACO participants and/or ACO

providers/suppliers necessary, or between the ACO, its participants or ACO providers/suppliers and entities or individuals outside the ACO, for and directly related to operating the ACO and achieving the integrated care or the cost savings and quality goals of the program;

- Distributions of shared savings and similar payments received from private payers;
- Other financial relationships for which a waiver would be necessary;
- Additional or different waivers needed in the context of the "two-sided" risk model to avoid either overutilization or stinting on care, and the need to cover such arrangements as escrow accounts, surety bonds, and letters of credit that may be used in connection with risk models;
- Whether arrangements that occur after the sunset date of 2013 but otherwise comply with the existing Stark exception and Anti-Kickback safe harbor relating to electronic health records arrangements should be protected; and
- Whether it will be necessary to extend the waivers to the provisions of the fraud and abuse laws relating to beneficiary inducements.

Observations Regarding CMS/OIG Notice Pertaining to Waiver Designs. As anticipated in the lengthy list of arrangements on which CMS and OIG solicit additional public comments pertaining to its waiver authority for the Shared Savings Program, some providers contemplating the formation of ACOs are likely to be disappointed in the narrow scope of the proposed waivers pertaining only to distributions of shared savings payments:

- Although specifically mentioned in the solicitation of public comments, CMS and OIG have offered no clear plan as to how they would approach waivers with respect to such major areas of interest as payments and benefits that may be needed to start up an ACO (particularly for small physician groups that will not have significant capital to invest in such a venture) and protection for participation in private payor arrangements similar to the Shared Savings Program ACOs.
- The proposed Gainsharing CMP waiver does not extend to any party outside the ACO. Payments other than distributions of shared savings need to be paid consistent with an existing Stark exception. No mention is made of finalizing the proposed Stark exception for shared savings and incentive payments, as proposed in 2008.
- Existing exceptions under the fraud and abuse laws for electronic health records are limited in more respects than the sunset date referenced in the notice (*e.g.*, restrictions on donation of hardware; requirements for cost sharing by physicians). No mention is made in this notice of allowing for some expansion of these exceptions to encourage the development of technology necessary for ACO operations.
- It is unclear how CMS and OIG would approach requests for advisory opinions involving financial relationships not specifically covered under the ACO waiver rules, and whether any expedited review of such arrangements will be available.

Solicitation of Comments on Waiver Design for CMI. The Affordable Care Act authorizes the creation of the CMI to test innovative payment and service delivery models to reduce program expenditures while enhancing the quality of care. The March 31 notice generally solicits public comments on the exercise of the separate waiver authority applicable to CMI demonstration and pilot projects, noting that such waiver authority applies only to CMI projects and not to other arrangements. No proposed waivers are described in the notice.

IRS Notice 2011-20. On March 31, 2011, the IRS issued Notice 2011-20 soliciting comments as to whether existing guidance relating to tax-exempt organizations is sufficient for those planning to participate in the Medicare Shared Savings Program through an ACO, and what additional guidance may be necessary. The notice provides a brief overview of existing law applicable to tax-exempt organizations, including standards for recognition of exemption under Section 501(c)(3) (including private inurement to "insiders," service of public—as distinguished from private—purposes and

benefits, and the "promotion of health" as a "charitable" purpose); attribution of activities of a wholly-owned LLC to its exempt owner; definitions of unrelated business taxable income; and standards for an exempt organization's participation in partnerships with private entities.

The notice further sets out certain expectations of the IRS with respect to an exempt entity's participation in an ACO:

- A tax-exempt organization's participation in an ACO with private parties (including "insiders") would generally not be considered to result in private inurement or impermissible private benefit to the private party participants if certain conditions were met:
    - The terms of the exempt entity's participation are set out in a written agreement (including its share of savings payments, losses and expenses) negotiated at arm's length;
    - CMS has accepted the ACO into the Shared Savings Program (and thus, has continuing oversight and regulation of the ACO);
    - The exempt entity's share of economic benefits from the ACO is proportional to its benefits/contributions to the ACO (including receipt of an ownership interest proportional and equal in value to its capital contributions to the ACO, and receipt of returns of capital, allocations and distributions in proportion to its ownership interest);
    - The exempt entity's share of ACO losses does not exceed the share of ACO benefits to which the entity is entitled; and
    - All contracts and transactions involving the exempt entity, the ACO and ACO's participants, including the ACO's contracts with its participants and other parties, are at fair market value.
- Absent inurement or impermissible private benefit, shared savings payments received from an ACO would not be considered unrelated business taxable income to the exempt entity so long as the ACO meets all of the eligibility requirements established by CMS for the Shared Savings Program.

The IRS specifically solicits comments on the treatment of activities of an exempt entity through an ACO that are not related to the CMS Shared Savings Program, such as transactions with private plans. The IRS requests comments on how such activities would be substantially related to an exempt purpose, particularly in the absence of regulatory requirements imposing quality standards and oversight by a government agency of such activities outside of the Shared Savings Program.

The IRS commentary on the Shared Savings Program places great emphasis on the charitable activities arising from lessening the burdens of government and the safeguards present in a program that is overseen and monitored by CMS. At the same time, the standards for participating in ACOs would restrict the ability of exempt providers to subsidize other participating providers (such as small physician groups) in contributions to capital and sharing of ACO overhead expenses or losses in order to facilitate their participation. It is unclear from the limited authority cited in this notice how the IRS would apply the various guidance issued over the years with respect to joint ventures to ACO formation and to similar activities outside the context of the Medicare Shared Savings Program. The IRS notice serves as a reminder that organization of ACOs, even with the benefit of fraud and abuse law waivers, will require significant planning when a tax-exempt organization is involved as a participating provider.

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CMS to Change Rule Requiring Physician Signatures on Clinical Diagnostic Lab Tests – On March 31, 2011, CMS informed its Provider Resource mailing list that it intends to change the regulation requiring physician or qualified non-physician practitioner signatures on requisitions for clinical diagnostic laboratory tests paid under the clinical laboratory fee schedule. According to CMS, this change, due by the end of the year, stemmed from concerns that physicians, qualified non-physician practitioners, and clinical diagnostic laboratories were having difficulty complying with the

regulation. The text of the email may be found **here**.

CMS outlined its interpretation of 42 C.F.R. § 410.32 to require signatures on acquisitions for clinical diagnostic laboratory tests in the November 29, 2010, Medicare Physician Fee Schedule final rule. 75 Fed. Reg. 73170, 73483 (Nov. 29, 2010). The final rule required that the paperwork provided by physicians to clinical diagnostic laboratories that identified the test(s) to be performed contain the physician's (or qualified non-physician practitioner's) actual signature. On December 20, 2010, CMS informed contractors that many of the parties covered by this regulation were either unaware of the rule or did not properly understand the rule. Therefore, CMS told its contractors, the agency would spend the first quarter of 2011 conducting an educational campaign before enforcing the regulation. During the first quarter, however, CMS decided to focus on changing the rule rather than on educating affected entities.

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CMS Removes Restrictions on Investments By Captive Insurers – Following the D.C. Circuit's 2010 ruling in favor of K&S client Catholic Health Initiatives, CMS has removed a provision in the Provider Reimbursement Manual (§ 2162.2.A.4) governing reimbursement for malpractice and other liability insurance premiums paid to an offshore captive insurer. The former manual provision restricted the investments in equity securities by these foreign captives to ten percent of their assets and imposed additional limitations on how that ten percent may be invested. On August 13, 2010, the D.C. Circuit Court of Appeals ruled that the Manual's investment restrictions are invalid. *See Catholic Health Initiatives v. Sebelius*, 617 F.3d 490 (D.C. Cir. 2010). K&S lawyers Chris Keough, Paul Clement and Harry Richards represented the hospitals in that case.

The August 16, 2010, *Health Headlines* reporting on the underlying case is available **here**. The CMS transmittal is available by clicking **here**, and a copy of the Court's opinion is available by clicking **here**.

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CMS Issues Additional Guidance On Suspension of Medicaid Payments Pending An Investigation Of A Credible Allegation of Fraud – On March 25, 2011, CMS released an informational bulletin providing guidance on Section 6402(h)(2) of the Patient Protection and Affordable Care Act (PPACA). Section 6402(h)(2) of PPACA provides that States will not receive Federal financial participation (FFP) in the Medicaid program for items or services furnished by an individual or entity if the State has failed to suspend payments pending an investigation of a credible allegation of fraud, unless the State determines that "good cause" exists not to suspend payments. In addition, CMS released a set of frequently asked questions (FAQs) regarding Section 6402(h)(2) of PPACA. CMS released a final rule implementing this provision on February 2, 2011.

The informational bulletin provides guidance on what constitutes "good cause" for a State to determine not to suspend Medicaid payments or to discontinue an existing payment suspension. In addition, a State may impose a partial suspension of Medicaid payments if a good cause exception exists. According to the informational bulletin, good cause includes but is not limited to the following:

- Specific requests by law enforcement that State officials not suspend (or continue to suspend) payment.
- If a State determines that other available remedies implemented by the State could more effectively or quickly protect Medicaid funds than would implementing (or continuing) a payment suspension.
- If a provider furnishes written evidence that persuades the State that a payment suspension should be terminated or imposed only in part.
- A determination by the State agency that certain specific criteria are satisfied by which recipient access to items or services would otherwise be jeopardized.
- A State may, at its discretion, discontinue an existing suspension to the extent law enforcement declines to

cooperate in certifying that a matter continues to be under investigation and therefore warrants continuing the suspension.

- A determination by the State agency that payment suspension (in whole or in part) is not in the best interests of the Medicaid program.
- The credible allegation focuses solely on a specific type of claim or arises from only a specific business unit of a provider and the State determines that a suspension in part would effectively ensure that potentially fraudulent claims were not continuing to be paid.

CMS also released a set of FAQs regarding Section 6402(h)(2) of PPACA. Noting that States may have different considerations in determining what constitutes a credible allegation of fraud, CMS believes "States should have the flexibility to determine what constitutes a 'credible allegation of fraud' consistent with individual State law." In addition, CMS provides additional guidance on the potential sources of credible allegations of fraud. According to the FAQs, credible allegations can come from ***"any source,"*** including but not limited to: (1) Fraud hotline complaints; (2) Claims data mining; and (3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Given that referrals can come from ***any source***, it is conceivable that that Medicaid Integrity Contractors (MICS) and/or Medicaid Recovery Audit Contractors (Medicaid RACs) could make such referrals. CMS also notes the potential for mistaken or false reports of allegations of fraud, and thus "CMS encourages States to not solely rely on a singular allegation without considering the totality of the facts and circumstances surrounding any particular allegation or set of allegations."

A copy of the informational bulletin is available by clicking **here**. A copy of the FAQs is available by clicking **here**.

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DOJ Expands Blue Cross Antitrust Investigation – The Department of Justice (DOJ) is expanding its antitrust investigation of Blue Cross plans' use of most favored nations (MFN) clauses beyond Michigan into other states, according to media reports. DOJ and the State of Michigan filed a civil antitrust suit against Blue Cross Blue Shield of Michigan in October 2010 seeking to prohibit the Michigan Blue Cross plan from including or enforcing MFN clauses in its contracts with Michigan hospitals as an unreasonable restraint of trade under the Sherman Act. King & Spalding's *Health Headlines* analyzing the Michigan lawsuit is available by clicking **here**.

A DOJ spokesperson reported to the Wall Street Journal that "[t]he antitrust division is investigating the possibility of anticompetitive practices involving MFN clauses in various parts of the country," but declined to specify particular states or companies of interest. In response to that announcement, several media sources report that representatives for Blue Cross plans operating in Washington, D.C., Maryland, Northern Virginia, South Carolina and West Virginia confirmed recently receiving inquiries from the DOJ. Blue Cross plans in Ohio, Missouri and West Virginia also confirmed receiving civil investigative demands from state agencies. Representatives for the Kansas and North Carolina Blue Cross plans declined to confirm whether the plans received investigative demands.

This expansion of DOJ's and the States' investigations aligns with the DOJ's warning in October 2010 that its interest in MFN clauses could expand beyond Michigan. After announcing the Michigan probe, Assistant Attorney General for the Antitrust Division, Christine Varney, remarked: "[L]et me be clear, we will challenge similar anticompetitive behavior anywhere else in the United States." It remains to be seen whether DOJ and the States will conclude that the other Blues Plans' conduct also merits the initiation of antitrust litigation of the type pending against Michigan Blue Cross.

Reporter, *Jesica Eames*, Atlanta, +1 404 572 2821, jeames@kslaw.com.

Supreme Court Rules Safety Net Hospital Cannot Sue Under 340B Agreements – On March 29, the Supreme Court issued a unanimous opinion written by Justice Ruth Bader Ginsburg, which would prevent clinics and hospitals participating in the 340B prescription drug rebate program (340B Program) from suing drugmakers who overcharged such hospitals for prescription drugs. The case, *Astra USA, Inc. v. Santa Clara County*, was initiated by two California counties

in response to allegations that nine drugmakers had overcharged 340B Program-participating hospitals for prescription drugs. The overcharges were estimated to be more than $1 billion since 1999.

The 340B Program requires drugmakers whose drugs are covered by Medicaid to enter into Pharmaceutical Pricing Agreements (PPAs) with the Department of Health and Human Services, which obligate the drugmakers to provide their products to safety net facilities at the "best price." The Court acknowledged that evidence existed that the drugmakers had not given 340B Program entities their best price, and further that HHS and the Health Resources and Services Administration had failed to adequately monitor and enforce allegations of overcharging. However, the Court determined that the Veterans Health Care Act of 1992, which created the 340B Program, does not provide for a private right of action for participating entities to enforce the obligations under the program. The Court concluded that, given the lack of a private right of action under the statute, it would be "incompatible with the statutory regime" to allow participating entities to enforce the PPAs, which largely mirror the statutory language and obligations, as third-party beneficiaries. The Court said, "Though labeled differently, suits to enforce §340B and suits to enforce PPAs are in substance one and the same."

The decision overturned a ruling of the Ninth Circuit Court of Appeals, which would have allowed such lawsuits to proceed.

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King & Spalding Upcoming Roundtable on ACOs on April 15, 2011 – On Friday, April 15, 2011, we will be hosting a Roundtable in our Atlanta office from 1:00 p.m. - 2:30 p.m. Eastern Time titled ***Planning to Qualify As an Accountable Care Organization: Overview of Proposed Rules and Agency Announcements on Accountable Care Organizations***. The Roundtable will cover the much-anticipated proposed rule recently published by CMS regarding Accountable Care Organizations (ACOs). The Roundtable also will cover the OIG/CMS notice regarding waivers for certain ACO payments under the Stark, Anti-Kickback and Civil Money Penalties laws, and ACO-related announcements by the Federal Trade Commission, Department of Justice and the Internal Revenue Service released March 31, 2011.

In-person attendance is limited, so please register soon to reserve seats for your organization. We will again also offer a Webinar option for this Roundtable. You can register to attend the Roundtable by clicking **here**. Lunch will be provided between 12:00 p.m. and 1:00 p.m. before the Roundtable. We hope you will be able to join us.

General information on our practice is available at www.kslaw.com/health and in our electronic publications *Serving the Healthcare Industry* and *Healthcare Reform Task Force*. If you would like to be included on our regular healthcare practice mailing list to receive notices of other events and written updates, you can be added by submitting your full contact information to healthcare@kslaw.com.

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