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Obamacare Upheld: The Effect on Health Care Enforcement

By Mark S. Olinsky and Laura L. Hunt

After much anticipation and speculation, on June 28, 2012, the U. S. Supreme Court issued its decision regarding the constitutionality of two key provisions of the Patient Protection and Affordable Care Act (''ACA'') of 2010.[1]

To the surprise of many, Chief Justice Roberts joined with the ''liberal'' Justices in a 5–4 ruling upholding, as constitutional, ACA's individual mandate. Not surprisingly, in the days and weeks following its publication, there has been a frenzy of commentary, analysis, and discussion about the future impact of this decision.

As the dust settles, it is critically important for those in the health care industry—and the professionals who advise them—to remember that ACA is about much more than Medicaid expansion and the individual mandate.

Embedded within its 974 pages are a multitude of provisions that have significantly altered the health care regulatory landscape. More specifically, ACA has ushered in a new era of health care enforcement by implementing changes—and imposing new requirements—that have substantially increased the industry's compliance burden and the risk of becoming the target of a health care enforcement action by the Government (or an individual relator under the federal False Claims Act (''FCA'')).

The Office of Inspector General (''OIG'') of the Department of Health and Human Services (''HHS'') has previously stated that ACA ''makes a number of changes to the Medicare program that enhance [OIG's] efforts to recover overpayments and combat fraud, waste and abuse in the Medicare program.''[2] The Supreme Court's recent decision means that those

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[1] Nat'l Fed'n of Indep. Bus. v. Sebelius, No. 11-393 (U.S. June 28, 2012), *available at* http://www.supremecourt. gov/opinions/11pdf/11-393c3a2.pdf; *see also* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified in scattered sections of 21, 25, 26, 29, 30, and 42 U.S.C.), amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (codified in scattered sections of 20, 26, and 42 U.S.C.).

[2] CMS Reporting and Returning of Overpayments, 77 Fed. Reg. 9179, 9180 (Feb. 16, 2012) (amending 42 C.F.R. pt. 401, 405), *available at* http://www.gpo.gov/fdsys/pkg/FR-2012-02-16/pdf/2012-3642.pdf.

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changes are, at least for the foreseeable future, here to stay.

In the wake of this decision, those affected by ACA should take a fresh look at its recently affirmed enforcement mechanisms. Thus, this article briefly examines six (6) significant enforcement provisions (among the many to choose from) contained in ACA and their effect on the enforcement landscape.

The Anti-Kickback Statute

Establishing a violation of the anti-kickback statute (''AKS'')[3], requires the government to prove that a defendant ''knowingly and willfully'' solicited or received remuneration (including any kickback, bribe, or rebate) to induce or reward referrals or to generate federal health care program business.

Furthermore, the widely adopted ''one purpose'' test, first announced in *United States v. Greber*, [4] and wholeheartedly embraced by the government, provides that if one purpose of the remuneration (or payment) was to induce or reward referrals, then the AKS has been violated.

Interestingly, however, the Supreme Court has never addressed the definition of ''willful'' under the AKS. Thus, over time, differing courts have adopted varying standards or thresholds of ''intent'' with respect to the conduct required to sustain an AKS criminal conviction.

In the Ninth Circuit, as announced in *Hanlester v. Shalala*,[5] the government was required to show the defendant: (i) knew the AKS prohibited the offering or paying of remuneration to induce referrals; and (ii) engaged in the alleged conduct with the specific intent to violate the AKS.

Other courts, like the Eleventh Circuit in *United States v. Starks*, [6] rejected the ''specific intent'' standard of *Hanlester* but, instead, required the government to prove that the defendant knew, at least generally, that some part of the conduct was unlawful (*e.g.*, acting with a bad purpose) even if the defendant was not specifically aware that the conduct violated the AKS.[7]

These standards appear no longer to be available to individuals faced with alleged AKS violations. Section 6402(f)(2) of ACA amended the AKS to insert language clarifying that ''a person need not have actual knowledge of the AKS or a specific intent to violate it'' in order to support a conviction under the statute. In so doing, the general consensus is that ACA has legislatively overturned *Hanlester*, *Stark*, and their progeny.

While the issue of the AKS mens rea requirement post-ACA has thus far surfaced very sparingly in the courts, the cases that have dealt with the issue have simply quoted the amended language and moved on.

Of note, however, is a case from the United States District Court for the Northern District of Georgia, *United States v. Houser*,[8] which dealt with the retroactive use of the AKS for crimes committed pre-ACA amendments.

While not allowing retroactive use, in dicta the court noted that the ACA amendments ''arguably lessen[] the mens rea [requirements].'' Although it is clear that a defendant no longer must know that the conduct would violate the AKS, it is less clear if a defense still stands that the accused must know that the act is generally unlawful.

In any case, the government's now-substantially lowered burden of proof, when coupled with *Greber's* ''one purpose'' test, arguably paves a much smoother path for AKS prosecutions.

Reporting and Returning Overpayments

Section 6402(a) of ACA established a new rule regarding the reporting and returning of overpayments that is generally referred to as the ''60-day rule.''

Found in Section 1128J(d) of the Social Security Act (''SSA''), the rule requires any person—broadly defined to include (among others) providers, suppliers, and Medicaid managed care organizations—who has received an overpayment from Medicare or Medicaid to report and return the overpayment to an appropriate recipient (*e.g.*, a fiscal intermediary) within a specified (and short) period of time.

For most persons, the ''specified period of time'' requires reporting and returning of the overpayment within sixty (60) days of its identification. Cost-reporting entities, such as hospitals, are required to report and return an overpayment on the later of: (i) 60 days after identification; or (ii) the date any corresponding cost report is due.

In short: the risks and liabilities associated with exceeding the "60-day" rule are substantial and potential overpayments identified by a provider deserve diligent and timely attention.

More concerning than the daunting task of determining when an overpayment is ''identified'' (which is not clarified in ACA) and whether the overpayment can be sufficiently investigated and quantified so as to be ''reported and returned'' within the required two-month period is that failure to do so within the statutory timeframe exposes the noncompliant provider to liability under the FCA.[9] This is because the failure to timely report and return an overpayment creates an ''obligation'' under the FCA and subjects the provider potentially to criminal and/or civil liability. Even if a provider escapes criminal prosecution, the FCA's treble damages (effectively requiring a provider to reimburse the government three times the amount of the overpayment) are not an insignificant concern.

Moreover, notwithstanding the exposure risks under the FCA, failing to timely report and return could nevertheless subject the provider to civil monetary penal-

[3] 42 U.S.C. § 1320(a)-7(b) (2012).
[4] 760 F.2d 68, 72 (3d Cir. 1985).
[5] 51 F.3d 1390 (9th Cir. 1995).
[6] 157 F.3d 833 (8th Cir. 1998).
[7] *See also* United States v. Jain, 93 F.3d 436, 440 (8th Cir. 1996) (''Willfully means unjustifiably and wrongfully, known to be such by defendant Jain'' but also affirming that '' 'good faith' was a defense to the charge'').
[8] United States v. Houser, No. 4:10-CR-012-01-HLM, 2011 BL 135762, at *28 (N.D. Ga. May 23, 2011).
[9] 31 U.S.C. § 3729(a)(1)(G) (2012).

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ties and/or exclusion from Medicare and Medicaid under other statutory authorities.

In short: the risks and liabilities associated with exceeding the ''60-day'' rule are substantial and potential overpayments identified by a provider deserve diligent and timely attention.

Adding to the problem, on Feb. 16, the Centers for Medicare & Medicaid Services (''CMS'') published proposed regulations implementing—and in many ways broadening—the statutory rule.[10]

Although the proposed regulations apply only to providers and suppliers under Medicare Part A and Part B, if finalized as proposed, the regulations will affect a wide variety of providers and suppliers including, but not limited to: hospitals, physicians, durable medical equipment suppliers, long-term acute care hospitals, home health companies, and skilled nursing facilities, to name a few.

There are a handful of significant provisions contained in the proposed regulations that have created substantial concern within the provider community and which—if adopted as proposed—will substantially increase compliance burdens and costs.

First, the proposed rule broadly defines ''identified'' to include actual knowledge and acting in reckless disregard, or with deliberate indifference, of the existence of an overpayment.

Second, the proposed rule creates and establishes a broad—and undefined—''duty to investigate'' and to make ''a reasonable inquiry'' regarding the existence of potential overpayments.

The threshold for triggering this duty is disconcertingly low: CMS's proposed rule suggests that a hotline complaint (without any minimum threshold regarding the credibility of the complaint) is sufficient. CMS's proposal suggests that providers have a duty to investigate and reasonably inquire into each and every hotline complaint. This enhanced duty to investigate will substantially increase providers' compliance costs (both in time and money).

Third, CMS has proposed that all ''reasonable inquiries'' must be conducted with ''all deliberate speed'' after information about a potential overpayment is received by the provider.

What constitutes ''deliberate speed'' is not defined in the proposed rule. However, CMS is quick to clarify that failing to conduct a ''reasonable inquiry'' with all ''deliberate speed'' after receiving potential overpayment information (*e.g.*, a hotline complaint) could result in the provider ''identifying'' an overpayment for purposes of triggering the 60-day rule. Internal compliance investigations seldom proceed quickly.

They often involve a detailed review of voluminous business records and frequently include engaging outside counsel and consultants. Unfortunately for affected providers, CMS's proposed rule does not clarify whether acting with ''deliberate speed'' encompasses, for example, beginning an investigation within days of receiving potential overpayment information where that investigation is not concluded for several months.

Finally, CMS is proposing a 10-year lookback. This means that providers would be required to report and return overpayments if the overpayment is identified within 10 years of its receipt.

Not only is the proposed lookback burdensome for providers, but it also substantially interferes with the long-standing (and reasonable) expectation held by providers regarding the administrative finality of processing their claims.

Furthermore, the lookback directly conflicts with existing CMS regulations regarding the reopening of claims and the ''without fault'' rules under Medicare. In short, if adopted as proposed, the 10-year lookback will substantially increase administrative burdens associated with claims processing in addition to exposing providers to significant refund obligations.

Mandatory Medicaid Payment Suspension

State Medicaid programs have always had the authority to suspend provider payments in cases of fraud or willful misrepresentation; however, ACA has converted that permissive authority into a mandatory rule. Section 6402(h) of ACA, amending Section 1903(i)(2) of SSA, requires the automatic suspension of provider payments pending investigations of credible allegations of fraud unless good cause (as defined in the regulations) not to suspend payments exists.

State Medicaid programs that fail to invoke this mandatory suspension rule are not entitled to receive their Medicaid Federal Funds Participation payments from the Government. CMS amended the regulations governing this rule on Feb. 2. [11]

A ''credible allegation of fraud'' is any allegation, which has been verified by the state, from any source, including: fraud hotline complaints, claims data mining, patterns identified through provider audits, civil false claims actions, and law enforcement investigations. Allegations are considered credible if they contain ''indicia of reliability'' and the state Medicaid agency has reviewed all allegations, facts and evidence carefully and acts judiciously on a case-by-case basis.

Importantly, however, the new rule has lowered the threshold of proof necessary to identify a ''credible allegation of fraud'' in contrast to the heightened requirement of ''reliable evidence'' contained in the prior regulation. This change suggests that provider payments will be suspended with greater frequency and such decisions will likely be based upon less evidence.

Affected providers should not expect to receive notice of the suspension decision until after it has been implemented. This is because the regulations do not require pre-suspension notice. Post-suspension notices are required within five (5) days unless law enforcement requests a delay in notification.

The notice must: (i) identify the general allegations underlying the suspension decision; (ii) specify, when applicable, the type(s) of Medicaid claims or business affected by the suspension; (iii) inform the provider of its right to submit written evidence (*e.g.*, a rebuttal statement) challenging the decision; and (iv) inform the provider of its appeal rights.

Payment suspensions are temporary, but not restricted to a maximum number of days (unlike Medicare, which provides that suspensions are generally limited to 180 days). Instead, states have been given the flexibility to decide the duration of payment suspen-

[10] CMS Reporting and Returning of Overpayments, 77 Fed. Reg. at 9179.

[11] 42 C.F.R. § 455.1 (2012).

sions in order to accommodate state laws and legal processes.

The only basis for challenging a payment suspension decision is to argue that good cause exists not to suspend—or only to partially suspend—payments.

What constitutes ''good cause'' is expressly outlined within the regulation and includes, for example: (i) suspension jeopardizes beneficiary access to care; (ii) suspension is not in Medicaid's best interest; and (iii) there are other remedies implemented by the State that more effectively or quickly protect Medicaid funds.

There is not, however, any provision in the regulation for the provider to challenge the underlying ''credible allegation of fraud'' as a basis for overturning the suspension decision.

Finally, state Medicaid programs are required to make fraud referrals to the Medicaid Fraud Control Unit (''MFCU'') each time they suspend payments under this rule. Thus, providers that receive a Medicaid notice of payment suspension should prepare themselves for future contact by the MFCU.

Increased Self-Disclosure

As required by Section 6409(a) of ACA, HHS developed and implemented a Self-Referral Disclosure Protocol (''SRDP'') on or about Sept. 23, 2010,[12] which established a mechanism under which providers and suppliers can self-disclose violations of the Stark law (''Stark'').[13]

Stark is a strict liability statute that prohibits physicians from referring Medicare patients for certain designated health services (''DHS'') paid for by Medicare if the referring physician (or an immediate family member) has a financial (ownership, investment or compensation) relationship with that DHS entity.

Only if the physician strictly complies with one of the regulatory exceptions to the general rule of prohibition will otherwise prohibited referrals be permitted and properly paid for by Medicare. If the arrangement fails to satisfy just one element of the designated exceptions, the arrangement is deemed to violate Stark.

This is true for even the most innocuous of oversights (*e.g.*, neglecting to renew an expired lease agreement between a physician and a hospital). Thus, ACA implemented the SRDP to facilitate the resolution of self-disclosed Stark violations.

Another purpose of the SRDP was to incentivize providers to proactively disclose actual or potential overpayments arising from Stark violations in exchange for potential leniency from HHS in the form of a reduced repayment obligation as part of any settlement. This leniency is not required by the SRDP, but rather, only discretionary.

Section 6409(b) grants HHS discretion to reduce the amount owed for a Stark violation. When making this determination, HHS may consider: (i) the nature and extent of the improper arrangement; (ii) the timeliness of self-disclosure; (iii) provider cooperation during the self-disclosure; (iv) the litigation risk associated with the disclosed matter; and (v) the financial position of the disclosing party.

The SRDP must be used in good faith and is available only for Stark violations. Overpayments identified as a result of violating other statutory authority—if appropriate for self-disclosure—are to be disclosed under OIG's self-disclosure protocol.[14]

It is important to remember that a Stark violation may also give rise to liability under the AKS, Civil Monetary Penalties Law, or even the False Claims Act. Furthermore, self-disclosure under the SRDP does not foreclose the possibility that CMS will refer the disclosure to OIG or the Department of Justice (''DOJ'') for further inquiry depending on the facts and circumstances of the conduct disclosed.

Providers are not permitted to simultaneously disclose the same conduct under both self-disclosure protocols, so careful attention must be paid when selecting the appropriate disclosure protocol for the circumstance at hand.

CMS emphasizes in its protocol that ''it is imperative'' for parties ''to disclose matters in a timely fashion once identified'' in light of ACA's new 60-day rule.[15]

If a provider utilizes the SRDP within 60 days of identifying the potential or actual overpayment, the SRDP will toll the provider's obligation to *return* the overpayment under the 60-day rule until a settlement agreement is executed. It does not appear that an SRDP disclosure will satisfy the duty to *report* the overpayment under the 60-day rule.

CMS's proposed regulations—discussed above—explicitly state that utilizing the SRDP will not satisfy the obligation to report the overpayment. Thus, if adopted as proposed, providers utilizing the SRDP will also be required to disclose separately (by whatever procedure is adopted) the identified overpayments under the 60-day rule.

The extent to which the SRDP is achieving the purposes envisioned by ACA's drafters is unclear. Publically available settlement data suggest the mechanism has been met by providers with caution and that its use has not been widely embraced within the industry.

To date—nearly two years after implementation—there have only been 10 CMS settlements through the SRDP. Of those, eight (8) settlements involved hospital disclosures, and the remaining two (2) were disclosed by physician group practices.[16]

Furthermore, CMS provides few details about the settlements other than the total settlement amount and the general nature of the Stark violation (*e.g.*, failure to satisfy the requirements of the personal services exception).

Thus, it is difficult (if not impossible) to assess the frequency with which CMS exercises its discretion for leniency in calculating the overpayment owed or to quantify the value of that leniency against the disclos-

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[12] Ctr. for Medicare & Medicaid Serv., CMS Voluntary Self-Referral Disclosure Protocol (2012) [hereinafter CMS, SRDP], *available at* https://www.cms.gov/Medicare/Fraud-and Abuse/PhysicianSelfReferral/ downloads/6409_SRDP_ Protocol.pdf.

[13] 42 U.S.C. 1395(n)(n) (2012).

[14] OIG Provider Self-Disclosure Protocol, 63 Fed. Reg. 58399 (Oct. 30, 1998), *available at* http://www.gpo.gov/ fdsys/pkg/FR-1998-10-30/pdf/98-29064.pdf.

[15] *See* CMS, SRDP *supra* note 12, at 6.

[16] *Self-Referral Disclosure Protocol Settlements*, Ctr. for Medicare & Medicaid Serv., https://www.cms.gov/ Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.html (last visited July 18, 2012).

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ing provider's potential exposure had it not utilized the SRDP.

Finally, under the current SRDP framework, the scope (*e.g.*, lookback) of a disclosing physicians' financial reporting requirement is limited to the now-existing timeframes contained in Medicare's claims reopening regulations.[17]

That is, physicians need only ''lookback'' four (4) years when calculating the total amount of prohibited remuneration to be reported under the SRDP. The 60-day rule regulations, if finalized as proposed, will dramatically change this scope.

Indeed, if reopening regulations are amended (as suggested) to include the proposed 10-year lookback, then physicians disclosing under the SRDP will be required to ''lookback'' an additional six (6) years when quantifying the overpayment amount.[18]

This is but another example of ACA's impact on the health care enforcement landscape.

Mandatory Compliance Programs

Gone are the days of voluntary compliance programs. Section 6401(a) of ACA amended the SSA to mandate that HHS implement requirements obligating providers and suppliers to establish compliance programs containing certain ''core elements'' (potentially varying across provider type) as a condition of participation (*e.g.*, enrollment) in Medicare.[19]

ACA contains no implementation timeline for the required compliance programs, but providers currently lacking such programs are well advised to initiate the process of developing them.

In contrast to other providers and suppliers, Medicare skilled nursing facilities and Medicaid nursing facilities are required to implement their compliance programs no later than March 23, 2013, which must contain the eight core elements outlined in Section 6102 of ACA.

Although ACA does not outline the required ''core elements'' in the mandated compliance programs (to be developed in consultation with the OIG) for all providers, it would come as little surprise if the core elements: (i) mirrored those in ACA applicable to nursing facilities; and (ii) shared elements culled from OIG's pre-ACA compliance program guidance.[20]

Furthermore, on Feb. 2, 2011, CMS solicited comments on the use ''of the seven elements of an effective compliance program'' described in the Federal Sentencing Guidelines ''as the basis for the core elements'' of the compliance programs required by ACA.[21]

To date, CMS has not finalized thoese regulations; however, those elements (and pre-existing OIG guidance) are certainly an excellent source of guidance for proactive providers and suppliers developing and implementing programs in advance of any final rule.

Increased Enforcement Funding

Finally, ACA further deepened the government's coffers for investigating and prosecuting fraud, waste, and abuse in the federal health care programs by allocating an additional $350 million over the next ten (10) years to these enforcement efforts.

The return on this financial investment is not insignificant. HHS and DOJ announced in February 2012 that for Fiscal Year (''FY'') 2011, the federal government won (or negotiated) $2.4 billion in health care fraud judgments and settlements.[22]

Coupled with fraud enforcement efforts from prior years, the total amount of actual monetary deposits for FY 2011 totaled a record-setting $4.1 billion. Using an average of recoveries from 2009-2011, the federal government's actual return on investment (''ROI'') has been $7.20 for each $1.00 expended on enforcement.

Furthermore, in FY 2011, DOJ opened 1,110 new criminal and 977 new civil health care fraud investigations, while 743 defendants were convicted of health care fraud-related crimes.

FCA recoveries are anticipated to hit a record high in 2012, with health care cases leading the way. Indeed, just this month, GlaxoSmithKline LLC (''GSK'') entered into a $3 billion settlement with the DOJ, representing the largest health care fraud settlement ever in the United States.[23]

The settlement includes, among other things: (i) a guilty plea in connection with GSK allegedly promoting off-label uses of Paxil, Wellbutrin and Avandia; (ii) paying $1 billion in criminal fines and restitution ($956,814 of which is the fine); and (iii) paying $2 billion to resolve civil liabilities under the FCA.

Touted as a ''major milestone'' in the Government's ''efforts to stamp out health care fraud,'' this settlement is a poignant reminder to industry providers and suppliers that ACA, in concert with other statutory authorities, has forever altered the landscape of health care enforcement and the risks are greater than ever before.

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[17] *See* CMS, SRDP *supra* note 12; *see also* 42 C.F.R. § 405.980(b) (2012).

[18] Centers for Medicare & Medicaid Services, Voluntary Self-Referral Disclosure Protocol: Frequently Asked Questions (2012), *available at* https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/ Downloads/ FAQsPhySelfRef.pdf.

[19] Patient Protection and Affordable Care Act § 6401(a); 42 U.S.C. § 1320(a)-7(j) (2012).

[20] *Compliance Guidance*, Office of the Inspector Gen., Dep't of Health and Human Serv., http://oig.hhs.gov/ compliance/ compliance-guidance/index.asp (last visited July 18, 2012).

[21] CMS Suspensions and Compliance Plans for Providers and Suppliers, 76 Fed. Reg. 5862 (Feb. 2, 2011) (amending 42 C.F.R. pt. 1007), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-02-02/pdf/2011-1686.pdf; U.S. Sentencing Guidelines Manual § 8B2.1 (2011), *available at* http://www.ussc.gov/ Guidelines/2011_Guidelines/ Manual_PDF/Chapter_8.pdf.

[22] U.S. Dep't of Justice & Dep't of Health and Human Serv., Health Care Fraud and Abuse Control Program Annual Report FY 2011 (2012), *available at* http://oig.hhs.gov/publications/ docs/hcfac/ hcfacreport2011.pdf.

[23] Press Release, U.S. Dep't of Justice, GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), *available at* http://www.justice.gov/opa/pr/2012/ July/12-civ-842.html.