By Sandi Krul, Co-Chair of the Hooper, Lundy & Bookman Diversity Initiative

In response to a growing lifestyle disease epidemic over the last several decades, and the resulting adverse impact on employee health and well-being, there is increased interest in employer-based wellness programs, as well as employer-based health clinics. According to RAND Health’s Workplace Wellness Programs Study Final Report (2013), recognizing that these chronic conditions lead to lowered productivity due to absence from illness (absenteeism) and reduced performance even while at work (presenteeism), as well as the associated increase in health care coverage costs and reduced competitiveness in the marketplace, about half of all U.S. employers with 50 or more employees offer workplace wellness programs.

As is the case with health care programs and facilities generally, these employer-sponsored wellness programs and health clinics are subject to a complex regulatory framework. A significant portion of that regulatory framework focuses on health care related regulatory issues such as the corporate practice of medicine and fraud and abuse laws. However, employer-based health programs must also comport with the myriad of state and federal non-discrimination rules, including those promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Patient Protection and Affordable Care Act (the ACA) and the June 2013 final regulations respecting Incentives for Non-discriminatory Wellness Programs in Group Health Plans at 78 FR 33158 (the 2013 Final Regulations), as well as Title I of the Americans with Disabilities Act (ADA), enforced by the Equal Employment Opportunity Commission (EEOC). This article will examine these HIPAA and ADA non-discrimination rules as applicable to employer-based wellness programs, including the EEOC’s new proposed rule specifically addressing the use of incentives in employer-based wellness programs under the ADA.

HIPAA Anti-Discrimination Requirements for Wellness Programs.

HIPAA (as modified by Section 1201 of the ACA and the 2013 Final Regulations), prohibits discrimination in group health plans (premiums, benefits or eligibility) based on any health factor, and employer-sponsored wellness programs that are part of a group health plan are subject to that antidiscrimination prohibition. However, an exception to that general prohibition allows

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premium discounts, rebates or modifications to otherwise applicable cost sharing (including copayments, deductibles or coinsurance) in return for adherence to certain programs of health promotion and disease prevention. In applying that exception, HIPAA’s anti-discrimination laws distinguish between two types of wellness programs – participatory wellness programs and health-contingent wellness programs.

Participatory wellness programs either do not provide a reward, or do not include any conditions for obtaining a reward that are based on an individual satisfying a standard related to a health factor. Participatory wellness programs are permissible under HIPAA nondiscrimination requirements if available to all similarly situated individuals.

Health-contingent wellness programs, on the other hand, may be either “activity-only” (i.e., require individuals to perform or complete an activity related to a health factor in order to obtain a reward, but do not require an individual to attain or maintain a specific health outcome) or “outcome based” (i.e., require individuals to attain or maintain a standard related to a health factor to obtain a reward, such as not smoking or attaining certain results on a biometric screening, or require an individual to undertake more than a similarly situated individual based on a health factor to obtain the same reward). Under HIPAA regulations and guidance, these health-contingent wellness programs must meet the following requirements: (1) give all individuals eligible for the health-contingent wellness program the opportunity to qualify for the reward at least once a year, (2) the total reward offered to an individual cannot exceed 30 percent of the total cost of employee-only coverage under the plan (or 50 percent if attributed to tobacco prevention or reduction), (3) be reasonably designed to promote health or prevent disease, (4) the full reward must be available to all similarly situated individuals, and (5) plans and issuers must disclose the availability of a reasonable alternative standard to qualify for the reward in all plan materials and disclosures.

The 2013 Final Regulations recognize that an employer-based wellness program’s compliance with HIPAA nondiscrimination rules (as amended by the ACA), including the wellness program requirements described above, is not determinative of compliance with any other provision of state or federal law, including, but not limited to, the ADA wellness program requirements. Of course, the programs must be administered in compliance with HIPAA’s Privacy, Security and Breach Notification requirements set forth in 45 CFR part 160 and part 164.

**ADA Anti-Discrimination Requirements and New Proposed Rule for Wellness Programs.**

The ADA prohibits discrimination against individuals on the basis of disability, “in regard to… employment compensation… and other terms, conditions, and privileges of employment,” including employee benefits such as health insurance benefits, regardless of whether such benefits are administered by the covered entity. Absent undue hardship, Title I of the ADA also requires employers to provide reasonable accommodations (modifications or adjustments) to enable employees with disabilities to earn whatever financial incentive an employer or other covered entity offers (irrespective of whether a wellness program includes disability-related inquiries or medical examinations), so that individuals with disabilities have equal access to the benefits offered to employees without disabilities.

Title I of the ADA further limits an employer’s ability to make disability-related inquiries, and from requiring medical examinations, unless such inquiry or examination is shown to be job-related and consistent with business necessity. The ADA provides an exception to this limitation, allowing for “voluntary” medical examinations, including “voluntary” medical histories, which are part of an employee health program available to employees at the worksite. However, until now, there was limited guidance on the interplay between financial incentives in wellness programs and the ADA.

The EEOC’s interpretation of the term “voluntary” in the ADA’s disability-related inquiries and medical examinations provision is central to the interaction between the ADA and HIPAA’s wellness program provisions, as amended by the ACA. Because of insufficient guidance on this issue in the ADA, the EEOC issued a proposed rule on April 16, 2015, to amend the implementing regulations of Title I of the ADA (at 29 CFR Part 1630), and related interpretative guidance, respecting employer wellness programs (the “Proposed Rule”). The Proposed Rule addresses the extent to which incentives (both financial and non-financial incentives such as time off, prizes and other items of value) might affect the voluntary nature of such wellness program.

More specifically, the Proposed Rule addresses the extent to which employers may utilize incentives as a means of encouraging employee participation in wellness programs, when those programs include disability-related inquiries and/or medical examinations. The Proposed Rule helps to bring the ADA in line with HIPAA, as amended by the ACA and related regulations (which established the 30 percent incentive limit under HIPAA - 50 percent if attributed to tobacco prevention or reduction).

(continued on page 4)
HLB is pleased to announce recognition by Chambers & Partners, The Legal 500 and SuperLawyers as a top law firm with top-rated lawyers in the United States, in California, and in Washington, D.C. Each organization uses some combination of peer recognition, interviews with Managing Partners and clients, and outside research.

Chambers & Partners
Chambers & Partners has recognized HLB as a top health law firm in the nation. As part of its research, Chambers recorded statements from clients, including: “A very good firm offering excellent, substantive advice.” And “Their healthcare regulatory advice is top-notch.” In addition, Chambers noted that HLB offers “significant expertise in long-term care matters as part of a broad healthcare practice.”

Chambers’ national recognition is in addition to the firm once again being recognized as a top tier firm in California. Along with firm recognition, Chambers also recognized the following attorneys as top in the field of health law.

**Nationwide**

**HC Regulatory & Litigation**
- Lloyd A. Bookman
- Patric Hooper
- M. Steven Lipton

**Recognized Transactional Practitioner**
- Robert W. Lundy

**California**

- Robert W. Lundy – *Eminent Practitioner*
- Lloyd A. Bookman
- John R. Hellow
- Patric Hooper
- M. Steven Lipton
- Charles B. Oppenheim
- Paul T. Smith
- W. Clark Stanton
- W. Bradley Tully

**District of Columbia**

- Robert Roth
- James Segroves (Up and Coming)

**Legal 500**
The Legal 500 has also recognized HLB as a top health law service provider in the United States. In addition to firm recognition, the Legal 500 also recognized the following attorneys: Patric Hooper Robert Lundy and Brad Tully in Los Angeles; Mark Reagan in San Francisco; William Eck and Robert Roth in Washington, D.C.

**Southern California Rising Stars**
Southern California SuperLawyers has recognized the following attorneys as health law Rising Stars: Eric Chan, Amanda Hayes-Kibreab, Jasmin Niku and Devin Senelick.
The Proposed Rule would adopt the following changes to the regulations and guidance at 29 CFR Part 1630:

(1) New proposed section 1630.14(d)(1) requires employee health programs, including any applicable disability-related inquiries and medical examinations, to be reasonably designed to promote health or prevent disease, and provides that a program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating employees, is not overly burdensome, is not a subterfuge for violating the ADA or other antidiscrimination laws, and is not highly suspect in the method chosen to promote health or prevent disease.

(2) New proposed section 1630.14(d)(2) defines when employee health programs with disability-related inquiries or medical examinations are “voluntary” in nature. In addition to not requiring employees to participate, to qualify as a “voluntary” program, a health program must:

— not deny coverage under any of its group health plans or particular benefits packages within a group health plan for non-participation, or limit the extent of benefits for non-participating employees (except to the extent the limitation may be the result of foregoing a financial incentive permitted under (d)(3) of the Proposed Rule).

— not take any adverse employment action or retaliate against, interfere with, coerce, intimidate, or threaten employees within the meaning of Section 503 of the ADA (at 42 U.S.C. §12203).

— if part of a group health plan, provide employees with a written notice that (A) the employee is reasonably likely to understand, (B) describes the type of medical information that will be obtained and the specific purposes for which the medical information will be used; and (C) describes the restrictions on the disclosure of the employee’s medical information, the employer representatives or other parties with whom the information will be shared, and the methods the covered entity will use to ensure that medical information is not improperly disclosed (including whether it complies with the measures set forth in the HIPAA regulations at 45 CFR parts 160 and 164).

(3) New proposed section 1630.14(d)(3) provides that the use of incentives (financial or in-kind) in an employee wellness program, whether in the form of a reward or penalty, together with the reward for any other wellness program that is offered as part of a group health plan, will not render the program “involuntary” provided that the maximum allowable incentive available under the program does not exceed 30 percent of the total cost of employee-only coverage (which generally tracks HIPAA and the ACA).

(4) Except as is permitted under (d)(4) and is necessary to administer the health plan, the new proposed section 1630.14(d)(6) requires that medical information or history obtained through the program’s disability-related inquiries or medical examinations be provided to an ADA covered entity in aggregate terms that do not disclose, or are not reasonably likely to disclose, the identity of any employee.

(5) New proposed section 1630.14(d)(7) provides that, compliance with the requirements of section 1630.14(d), including the limit on incentives under the ADA, does not relieve an ADA covered entity from its obligation to comply with the nondiscrimination provisions of Title VII of the Civil Rights Act of 1964, the Equal Pay Act of 1963, the Age Discrimination in Employment Act of 1967, the Genetic Information Nondiscrimination Act of 2008 and other sections of Title I of the ADA.

Under the Proposed Rule, former section (d)(1) is to be renumbered as (d)(4) and requires that the information obtained for employee health programs under paragraph (d), regarding the medical condition or history of any employee, be collected and maintained on separate forms and in separate medical files and be treated as a confidential medical record, except that: (i) supervisors and managers may be informed regarding necessary restrictions on the work or duties of the employee and necessary accommodations; (ii) first aid and safety personnel may be informed, when appropriate, if the disability might require emergency treatment; and (iii) government officials investigating compliance with this part must be provided relevant information on request. Similarly, former section (d)(2) is to be renumbered as (d)(5) and requires that information obtained under paragraph (d), regarding the medical condition or history of any employee, not be used for any purpose inconsistent with this part.

The full text of the Proposed Rule may be viewed at https://www.federalregister.gov/articles/2015/04/20/2015-08827/amendments-to-regulations-under-the-americans-with-disabilities-act

For additional information, please contact Sandi Krul in Los Angeles at 310.551.8137, Steve Phillips in San Francisco at 415.875.8508, Joseph LaMagna in San Diego at 619.744.7305 or Bob Roth in Washington, D.C. at 202.580.7700.

1 See Titles I and IV of HIPAA (adding Section 9802 of the Internal Revenue Code, Section 702 of ERISA, and Section 2705 of the Public Health Services Act); See also 42 U.S.C. § 300gg-4 and 45 CFR §146.121 (the HIPAA nondiscrimination provisions).
2 Id.
3 See 42 U.S.C. 12101 et seq.
Life After KBR: What the Supreme Court’s Recent False Claims Act Decision May Mean for the Health Care Industry

By James F. Segroves and Kevin N. Royer

On May 26, 2015, the Supreme Court of the United States answered two questions involving the False Claims Act (FCA). On its face, the case before the Court—Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter (KBR)—had nothing to do with health care. Instead, the underlying case involved alleged fraud by military contractors in Iraq. However, the answers provided by the Court could have a material impact on members of the health care industry facing investigations and litigation under the FCA.

The Court in KBR was asked to interpret the meaning of language in both the FCA and a fairly arcane statute known as the Wartime Suspension of Limitations Act (WSLA). Subject to certain exceptions not relevant here, the FCA contains a six-year statute of limitations. The FCA also provides that if a case is commenced by a whistleblower (as most are), “no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.” This latter provision is commonly known as the “first-to-file bar.”

The WSLA, in turn, provides that “[w]hen the United States is at war or Congress has enacted a specific authorization for the use of the Armed Forces, . . . the running of any statute of limitations applicable to any offense . . . involving fraud . . . against the United States . . . shall be suspended until 5 years after the termination of hostilities . . . .” The WSLA does not define what constitutes an “offense.”

The Court’s opinion in KBR contained two central holdings. First, the Court held that the WSLA does not suspend the running of the FCA’s statute of limitations. The Court reached this conclusion after finding that the WSLA’s use of the word “offense” refers to criminal violations only. Second, the Court held that the FCA’s first-to-file bar does not preclude a whistleblower’s lawsuit if the previous suit has been dismissed. This, the Court found, was the result required by the FCA’s use of the word “pending” to describe what type of action triggers the first-to-file bar.

As with any attempt to predict the future, prognostications regarding the impact of a Supreme Court decision can be notoriously inaccurate. However, logic and experience suggest that the Court’s decision in KBR could have certain positive and negative effects on the health care industry.

First, the Court’s decision with respect to the FCA’s statute of limitations provides much-needed clarity to defendants facing FCA litigation. Prior to the Court’s decision, whistleblowers and/or the Department of Justice (DOJ) could credibly argue that the relevant time period for purposes of discovery and quantifying the amount in controversy extended far beyond the six years before the initial complaint was filed. Now that the Court has spoken, defendants can more accurately assess the settlement value of cases and combat discovery that seeks information from time periods for which no FCA causes of action can be asserted.

Second, the Court’s interpretation of the FCA’s first-to-file bar could lead to repetitive, parasitic lawsuits brought by different whistleblowers seeking to take advantage of allegations made public by previously dismissed lawsuits. However, members of the health care industry would not be defenseless against such litigation tactics. For example, the FCA’s public-disclosure bar would likely preclude a later-filed suit where the whistleblower based his or her claims on allegations gleaned from public court filings in a previously filed federal action. While Congress recently amended the public-disclosure bar and gave DOJ discretion to waive the bar’s application, the public-disclosure bar remains a powerful tool for defendants facing litigation by whistleblowers with no firsthand knowledge on which to base their allegations.

Third, the Court’s interpretation of the first-to-file bar may have the salutary effect of slowing the proverbial “race to the courthouse” by whistleblowers’ counsel. If the Court had held that the first-to-file bar applies regardless of whether an earlier-filed action is dismissed, the strategy of file first and ask questions later would continue to be a rational one for whistleblowers’ counsel to follow, lest another whistleblower file their complaint first. However, now that the incentive to be first is somewhat diminished, it may cause whistleblowers’ counsel to exercise more care in deciding whether to commence litigation and, if so, what theories to pursue.

For additional information, please contact James Segroves in Washington, D.C. at 202.580.7710.

1 Kevin Royer is a current summer associate at Hooper, Lundy & Bookman and a law student at the UCLA School of Law.
6 2015 WL 2456621, at *5.
7 Id. at *5–8.
8 Id. at *8–9.
9 Id.
OIG Issues Fraud Alert on Physician Compensation

On June 9, 2015 the Office of Inspector General of the Department of Health and Human Services (OIG) issued a fraud alert warning that physician compensation arrangements may violate the federal anti-kickback statute. The fraud alert cautions physicians that they have a responsibility to insure that their financial relationships, such as medical director agreements, are for “bona fide services the physicians actually provide” and that “those arrangements reflect fair market value.” The OIG took the opportunity to publicize that it recently settled cases against 12 physicians who entered into medical director agreements and other arrangements which the OIG believed were for compensation to induce the physicians to refer or direct business to the entity paying the compensation to the physicians.

The anti-kickback statute is a criminal statute that prohibits “knowingly and willfully” providing anything of value to induce a person to refer or otherwise drive business to the person paying the compensation. The anti-kickback statute, which is enforced by the OIG, is often confused with the federal physician self-referral statute (the Stark law) which is a different federal law and is not a criminal statute. The Stark law is a strict liability law (where good intentions are not a defense), which requires physician financial relationships to fit into an exception in order for the physician to be permitted to refer Medicare patients for certain “designated health services” to the entity with whom the physician has the financial relationship. The Stark law has garnered significant attention in recent years for high-dollar settlements to which providers (but less frequently physicians) have been subjected.

This fraud alert draws attention back to the anti-kickback statute, and signals the OIG’s increasing willingness to pursue the physicians who receive compensation the OIG believes is suspect, instead of just the large organizations that compensate physicians. Historically, the OIG was more likely to go after big companies with “deep pockets” that pay physicians, rather than the physicians on the receiving end of the compensation arrangements. Now, the OIG is pursuing physicians more frequently. This fraud alert “encourages physicians to carefully consider the terms and conditions of medical directorships and other compensation arrangements before entering them.” Clearly, the OIG does not want physicians simply relying on the fact that a “big company” is offering them a contract, and concluding it therefore must be a legitimate arrangement.

For additional information, please contact Charles Oppenheim, David Henninger or Brad Tully in Los Angeles at 310.551.8111; Mark Johnson in San Diego at 619.744.7300; Ben Durie in San Francisco at 415.875.8500; or William Eck in Washington, D.C. at 202.580.7700.
## Calendar

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<tr>
<th>Date</th>
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<tr>
<td>June 3-5</td>
<td>National Institute of Trial Advocacy, Georgetown University Law Center</td>
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<td>Precious Murchison Gittens is faculty for the <em>Building Trial Skills</em> program</td>
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<td>June 11, 16, 17</td>
<td>CHA Hospital Finance and Reimbursement Seminar, Sacramento, Pasadena, Costa Mesa</td>
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<td>Led by Lloyd Bookman, HLB attorneys are primary faculty. Presenters include</td>
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<td>Lloyd Bookman &amp; Felicia Sze: <em>Medi-Cal &amp; Medicaid Updates</em></td>
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<td>John Hellow &amp; Jordan Keville: <em>Medicare Updates</em></td>
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<td>Katrina Pagonis &amp; Felicia Sze: <em>California Health Benefit Exchange Update</em></td>
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<td>June 23-26</td>
<td>2015 D.C. Circuit Judicial Conference, Philadelphia</td>
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<td>Precious Murchison Gittens represents HLB at this invitation-only event</td>
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<tr>
<td>June 30</td>
<td>A Roadmap to Diverse Leadership, Los Angeles</td>
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<td>HLB is sponsor of this educational event hosted by the Southern California chapters of WHA, HCE, AHCLA, NAHSE and NFLHE</td>
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<tr>
<td>July 22</td>
<td>2015 CAHF Summer Institute, La Costa</td>
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<td>Mark Reagan presents <em>Medical Decisions For Incapacitated Residents: An Update on Health &amp; Safety Code 1418.8</em></td>
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<tr>
<td>August 13</td>
<td>2015 Pharmerica Symposium, Chicago</td>
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<td>Mark Reagan presents <em>Managed Care Essentials for CEOs</em></td>
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The California Hospital Association (CHA) has just released the 2015 edition of the California Hospital Compliance Manual (CHC). Written by Hooper, Lundy & Bookman, PC, attorneys and CHA, the manual focuses on key components of an effective compliance program, including federal regulations, financial assistance policies, and other laws.

To order the new manual or for more information, see www.calhospital.org/compliance.