

Health Law ADVISORY

Current legal insights for health care executives

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Sins of Omission—Failure to Detect Excluded and Debarred Individuals and Entities

Exclusion statutes prohibiting billing Federal health care programs for services performed or ordered by excluded providers have been in effect for over thirty years.¹ The basic prohibition is that there is to be no Federal health care program payment for items or services furnished, ordered or prescribed by an excluded individual or entity. This includes orders written by another which are “directed by” an excluded provider whether billed separately, bundled, stated in a cost report, fee schedule or PPS system. The prohibition extends to administrative and management services which, while not directly related to patient care, are a necessary component of providing items and services to program beneficiaries.

Several years ago, CMS revised Form 855 to include language requiring enrolling providers and suppliers to state that they had in place a process to check both the OIG’s List of Excluded Individuals and Entities and the GSA’s list of persons and entities debarred from procurement and non-procurement programs. Following the

screening element of effective compliance programs set out in the Federal Sentencing Guidelines, each version of the OIG’s compliance program guidance has included such screening programs in its recommendations.

Out of concern that the screening requirements and the effect of exclusion were not well understood, in September 1999, the OIG issued a Special Advisory Bulletin entitled “The Effect of Exclusion From Participation in Federal Health Care Programs.”²

In addition, although a time standard for background checking does not appear in the statute, CMS sent letters to state Medicaid directors³ indicating that background checking for excluded individuals should be performed on a **monthly** basis. This monthly standard for background checking is not included in any of the OIG’s compliance program guidance except for the guidance for third party billers and has not generally been required in Settlement Agreements involving

² OIG-September 28, 1999.

³ SMDL #09-001 January 16, 2009 and SMDL #08-003 June 12, 2008.

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¹ Social Security Act 1128, (42 U.S.C. § 1320a-7a(6)) 1128A.

exclusion-related violations. Consequently, there is some ambiguity about how often providers and suppliers should conduct background checking.

The latest event to call attention to these long-standing background checking requirements is the enactment of the new refund requirements as part of the Patient Protection and Affordable Care Act (PPACA). Section 6402 of PPACA does not modify the basic prohibitions related to exclusion and background checking, but rather, puts into place a timeline for reporting and making repayments of any improperly received funds including those connected with an excluded or debarred provider or supplier.

PPACA Sec. 6402(d) requires overpayments to be reported and returned to the appropriate intermediary or carrier by the later of the date which is 60 days after the date on which the overpayment is identified; or the date any corresponding cost report is due, if applicable. The government's position seems to be that an overpayment is "identified" when the fact of an overpayment has been discovered, not the date received or the date on which the specific overpayment amount is calculated.

For example, on March 30th, "Hospital A", during a compliance audit, discovers that certain outpatient procedures were billed under an incorrect code, resulting in a higher reimbursement than was proper. After a couple of days of preliminary investigation, the coding error is confirmed. Even though the Hospital has not yet calculated the exact amount that was overpaid, the 60-day clock starts ticking on the date that the Hospital knows it had been overpaid by some unspecified amount.

Providers' and suppliers' vulnerabilities to

enforcement for overpayments stemming from employment or affiliation with excluded or debarred providers or suppliers have recently increased for several reasons:

1. Stepped-up Resources for Investigation and Enforcement. The additional dollars allocated to fraud and abuse enforcement under HIPAA and other Federal legislation have added human resources to investigation and enforcement functions and also made it possible for more sophisticated and efficient investigatory tools to be implemented. For example, regulators are now able to "data mine" claims data to compare provider numbers to the lists of excluded and debarred individuals and entities. In this way, billing attributed to excluded or debarred persons and entities is discovered without subpoenas of records or onsite investigations. The resulting enforcement action will typically involve a settlement agreement with the OIG whereby the improperly billed funds are recovered plus a multiple of that amount as a penalty for violation of the statute. Treble damages are possible where intentional actions (to bill for an excluded debarred person or entity) are found.

2. Medicaid-only providers and suppliers are especially vulnerable. In the quite recent past, the focus was on Medicare fraud and abuse and state Medicaid resources for investigation and enforcement were severely limited by lack of funds. As a result, Medicaid-only providers and suppliers (often social service agencies) were not as tuned-in to the OIG compliance guidance as Medicare providers and suppliers. Previously, the Federal government mostly deferred to the

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states for Medicaid fraud and abuse detection and enforcement and not much happened. Since the adoption of a Federal Medicaid Integrity Program, it is a stated policy of the OIG that the Federal government will assume a much-expanded role in policing the Medicaid program and in recovering improperly paid Medicaid funds. Federal budget allocations have been increased to this end and enforcement has started. Medicaid Integrity Contractors (MICs) are beginning to perform audits locally and local investigation of different aspects of improper payments are being conducted. During 2009 and 2010, there have been more than 32 settlement agreements and payments solely related to improperly billing Federal health care programs for items or services connected with an excluded individual or entity.

All Medicaid suppliers and providers need a written compliance program which includes procedures for background checking and follow-up actions.

- 3. We live in the trusting Midwest.** Generally, a very good thing, but it can create a false sense of security that potential employees and contractors have never had an exclusion issue, because “true” fraud and abuse is not common in this part of the country. Many exclusions are the result of professional licensure revocations rather than convictions for acts of fraud and abuse so the number of excluded individuals and entities in our communities may be higher than we expect.
- 4. The scope of the prohibition is quite broad.** The prohibition against even

indirect payment by Federal health care programs and the inclusion of management and administrative services which are a necessary component of providing services to Federal program beneficiaries, makes it very difficult to determine whether it will create undue risk to employ or contract with an excluded or debarred individual or entity. The conventional wisdom that the individual need only be kept out of direct services is not accurate and, if followed, will increase risk for the organization.

Julie A. Knutson

Health Sector Targeted by Employment Law Trends

As if the recent barrage of changes brought about by health care reform legislation wasn't enough, the health care industry is also the target of a number of changes in the area of employment law. As the Obama administration takes hold in the various agencies, the Department of Labor (DOL), the National Labor Relations Board (NLRB), the Equal Employment Opportunity Commission and the Office of Federal Contract Compliance Programs (OFCCP) have taken an approach to health care employers which presumes that employers are to be distrusted and are out to take advantage of the workforce. The theory seen over and over again is that only through strict government control can

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employers be expected to treat employees with respect.

While it has yet to be demonstrated whether or not the administration will accomplish the dramatic changes it desires, change is occurring. In the last few months, the following have been observed:

Wage and Hour

In the effort to bring about stimulus to the economy, the DOL was granted significantly more funds for enforcement. With the new funds and new investigators, the Wage and Hour Division of the U.S. Department of Labor has announced several initiatives nationwide which target health care employers. These initiatives are triggered by the perception from the DOL that health care is a low wage industry and lists the industry along with agriculture, day care, garment manufacturing, guard services and temporary help.

In these initiatives, Wage and Hour has targeted health care employers for investigation on such issues as:

- Meal periods interrupted by work whereby the entire meal period becomes compensable. Automatic deductions for meal periods are often the culprit in these violations.
- Misclassification of employees as exempt from overtime.
- Rounding practices with the time clock which end up in the employer's favor. While certain rounding is allowed, it is only allowed if the practice results in a neutral outcome.
- Bonuses, incentives or call time not included in the base rate for overtime purposes.
- Misclassification of workers as independent contractors rather than employees.

- Off-the-clock work, such as volunteering for work or being required to volunteer for certain functions.
- Pre-shift and post-shift activities which are part of the work setup or wind down, which are not compensated. This includes donning and doffing of protective clothing.
- Failure to include time worked at multiple locations such as the hospital and affiliated clinics for the purposes of overtime.
- Travel time from site to site during the workday.

The DOL recently settled an action with a Boston hospital for 2.7 million dollars to pay 700 employees lost overtime. In St. Louis, another health care employer paid 1.7 million dollars to settle with the DOL. Likewise, in the last few months, class action lawsuits have been filed against employers in Tennessee, Illinois, New York and Florida. In California, a class action claim against Kaiser Permanente was recently settled to pay employees improperly classified as exempt, the amount of 7.5 million dollars.

Affirmative Action

In what would be a significant extension of its authority, the OFCCP has recently indicated that it desires to revise regulations governing affirmative action for the disabled and veterans to the level currently required for affirmative action on the basis of race and gender. Under this extension of control, government contractor employers would be required to make inquiries to applicants as to their disability or veteran status, take affirmative action for placement and promotion, track employee progression through the system, and establish more detailed and elaborate programs in favor of these individuals.

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Union Organizing and the Employee Free Choice Act (EFCA)

Not only have unions put health care squarely in their sights for a number of years as a key target for growth, now, with a Congress and President who were elected with substantial union support, unions are seeking payback. For this reason, the government agencies are now seeking ways which will make it easier for unions to organize the nation's workforce, and with a particular focus on health care.

While the President and members of Congress pushed hard for the EFCA (which would strip employees of the right to vote on union representation), it fell just short. Now, with a Congress headed for what looks like a change in party control, *Politico* and the *Washington Post* have reported that an effort is underway which would provide for quick votes on such issues as the EFCA, between the date of the November election and the change in control of Congress in January. In this way, the likely-to-be-ousted Congress could pass the EFCA, leave the Congress with no alternative, and the new Congress would likely be a few votes shy of that necessary to overturn the legislation.

House members have begged Speaker Pelosi not to bring the EFCA back on the agenda prior to the election, but this lame duck vote approach seems to be the tactic which would satisfy these members facing election, and pay back the unions who are the number one contributors to the party in power.

If this doesn't work, the newest members of the NLRB, who were just appointed this winter, have stated that they don't need the EFCA in order to pursue major labor election reform. These members believe that they possess the right to "rule-making authority" which would allow them to

significantly alter the election process in favor of unions, without Congressional approval.

In addition, a priority for the new Board is to narrow the definition of "supervisor." This effort is twofold. First, by expanding the number of employees who can be in a union bargaining unit, unions widen their net of dues-paying members. Second, when employees who are supervisory in scope are now able to be used by unions as part of an organizing drive, it provides the union with credibility it may not otherwise possess.

Lastly, the Board is doing what it can to influence the extent of damages assessed in unfair labor practice cases. The Board has historically been rational in the assessment of damages. Recently, however, the Board announced a settlement with a non-union health care employer for the discharge of two workers, in the amount of \$900,000.

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Proposed Revisions to the Notice of Privacy Practices under HITECH:

Do We Have To Give Our NPP To Every Patient Again?

We have heard from many of you that the AHA and others are disseminating information that suggests that health care providers will be required to hand out its revised Notice of Privacy Practices (NPP) again (and obtain another acknowledgement) once changes are made to the NPP as required by the proposed rules implementing the HITECH Act.

Under the current Privacy Rule, there is **not** a requirement for health care providers with a direct treatment relationship to hand out and obtain acknowledgements for revised notices. The HITECH Act did nothing to alter the current Privacy Rule in this area.

This position is confirmed in the comments to the proposed rule implementing the HITECH Act changes to the Privacy Rule that were published on July 14, in the Federal Register. The comments were made

in the context of discussing the burden on covered entities to revise their notice and redistribute. The Office for Civil Rights notes:

Section 164.520(c)(2)(iv) requires that when “a health care provider with a direct treatment relationship with an individual revises the NPP, the health care provider must make the NPP available upon request on or after the effective date of the revision and must comply with the requirements of 164.520(c)(2)(iii) to have the NPP available at the delivery site and to post the notice in a clear and prominent location. We do not believe these requirements will be overly burdensome on health care providers and do not propose changes to them, but we request comment on this issue.”

We believe the confusion stems from the somewhat awkward manner in which the Privacy Rule is written. The Privacy Rule is written to first state the general rule that covered entities must “promptly revise and distribute its notice whenever there is a material change...” to the NPP. 145 C.F.R. 164.520164.520(b)(3). Many stop there with their analysis and assume that “distribute” means hand out again and obtain new acknowledgments. However, the general rule at (b)(3) must be read in conjunction with the implementation specifications for the distribution requirements at 145 C.F.R. 164.520(c). The implementation specifications indicate that, for providers that have a direct treatment relationship with an individual, whenever the notice is revised, the provider must make the notice available upon request on or after the effective date of the revision and promptly comply with the requirements that the provider have the notice available at the delivery site for individuals to request to take with them, and post the notice in a clear and prominent location where it is reasonable

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to expect individuals seeking service from the covered health care provider to be able to read the notice. 145 C.F.R. 164.520(c)(2)(iv). There is no requirement to give new NPPs to every patient or obtain acknowledgements that they have seen or read the revised NPP.

Vickie B. Ahlers

RACs to Begin Medical Necessity Reviews

CMS' New Issue Review Board recently approved the first "medical necessity review" audits under the permanent RAC program. The Region B recovery audit contractor, CGI, has posted several medical necessity review new issues on its website, opening the door for such audits to begin in Region B (IL, IN, KY, MI, MN, OH, WI). For example, syncope and collapse medical necessity reviews and MS-DRG validation were approved and added to the new issue list for Region B on August 6th. This issue, along with approximately 17 other inpatient hospital claims have been approved by CMS. The RACs in other regions are expected to get approval and begin the same reviews shortly.

The newest issue posted by HDI for Region D is a controversial one. HDI has begun its reviews of inpatient admissions without a physician's "inpatient admission order." In

the demonstration program, denials were issued if there was not a specific order for "admit to *inpatient*." While the issue is tied to medical necessity, this is not technically a medical necessity issue. Rather, its a billing requirement issue. If there is no order, there is not a billable inpatient admission. Denials in this area have sparked significant controversy over application of CMS regulations and program manuals, and whether case management protocols that assign the patient's admission status after reviewing the criteria is acceptable. Providers should be prepared to appeal RAC denials in this area as there is considerable room for challenge. Rural hospitals that utilize licensed mid-level practitioners to admit should watch for denials based on lack of a *physician's* inpatient admission order. The Medicare Claims Processing Manual, Section 50.3, states that "patients are admitted to the hospital as inpatients only on the recommendation of a physician or licensed practitioner permitted by the State to admit patients to a hospital." We anticipate that HDI may fail to address state law issues in its review of inpatient admissions. Keep a watchful eye over denials of claims for this reason and prepare to appeal.

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