Health Law Advisory

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OIG Exclusion Update: The Who, What, When, Where, and Why

The U.S. Department of Health and Human Services Office of Inspector General ("OIG") recently released an updated Special Advisory Bulletin[1] covering the scope and effect of exclusion from Federal health care programs. The updated bulletin replaces and supersedes the OIG's 1999 Special Advisory Bulletin on the effect of exclusion, and provides guidance on the scope of exclusion, civil monetary liability for employing or contracting with an excluded individual or entity, and tips for screening the List of Excluded Individuals and Entities ("LEIE").

Scope of Exclusions. Federal law provides that no Federal health care program payment may be made for items or services furnished by an excluded individual or at the medical direction or prescription of an excluded individual. The prohibition extends to all methods of Federal health care program payment, including payments based on cost reports, fee schedules, capitated payments, and prospective payments. The updated bulletin lists many examples where payment is prohibited, including: (i) when items or services are furnished by an excluded nurse (even if the services are included in the DRG payment and not billed separately); (ii) when items or services are furnished by an excluded physician who works at a hospital as a volunteer; and (iii) when an excluded pharmacist inputs billing information into an information system for drugs that are billed to a Federal health care program. The prohibition extends beyond items or services associated with patient care, and captures administrative and management services such as executive leadership, practice management, health information technology support, strategic planning, billing and accounting, and human resources, unless these services are wholly unrelated to Federal health care programs.

1 Available at https://oig.hhs.gov/exclusions/files/sab-05092013.pdf.

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Civil Monetary Penalty Liability. The OIG may impose civil monetary penalties ("CMPs") of up to $10,000 for each item or service furnished by an excluded individual, as well as an assessment of up to three times the amount claimed. The updated bulletin emphasizes that CMPs may be imposed if an excluded individual or entity participates in any way in the furnishing of items or services payable under a Federal health care program. The updated bulletin also points out that potential CMP liability exists where a hospital or other healthcare entity contracts with a staffing agency for temporary personnel. The OIG recommends that the entity itself screen contracted personnel, including nurses provided by staffing agencies, physicians and groups that provide coverage, and billing/coding contractors. Alternatively, the entity could rely on the outside agency's screening. However, the entity's CMP liability is not eliminated, and to reduce or eliminate CMP liability, the entity would need to demonstrate that it contractually relied on the staffing agency to screen the LEIE and that the entity did its own due diligence by requesting and maintaining screening documentation from the staffing agency. An entity that identifies potential CMP liability due to employing or contracting with an excluded individual or entity may use the OIG's new Provider Self-Disclosure Protocol to resolve the CMP liability.

Screening for Excluded Individuals and Entities. Prior to the updated bulletin, one of the most frequently asked questions by health care organizations was how often to screen the LEIE. The OIG notes that there is no statutory requirement to check the LEIE, and, ultimately, providers may decide how frequently to screen the LEIE. However, in the updated bulletin, the OIG states that it updates the LEIE monthly "so screening employees and contractors each month best minimizes potential overpayment and CMP liability." In addition, in 2009, the Centers for Medicare and Medicaid Services issued a letter to State Medicaid Directors directing states to require providers to screen all employees and contractors monthly. The updated bulletin recommends providers cross-check any LEIE findings by using the LEIE's social security number or Employer Identification Number ("EIN") verification function. The OIG plans to include National Provider Identifier ("NPI") information in the LEIE database. Finally, the OIG recommends that entities maintain documentation showing the results of LEIE searches performed.

Recommendations. Health care organizations that receive reimbursement or funding from Federal health care programs should review the updated bulletin and develop or revise policies and procedures to implement the new guidance as follows:

- Who? Confirm the exclusion status of all individuals and entities that furnish, order or prescribe any item or service, including administrative services, reimbursable through a Federal health care program. If contracting with an outside vendor or agency, ensure the contract addresses each party's obligation to screen for excluded individuals and to provide periodic reports to the other party. This applies to all types of Medicare and Medicaid suppliers and providers.

- What? Check (and double or triple check!) individuals and entities against the LEIE. Use broad search terms and maintain documentation of the LEIE searches performed (e.g., screen shots of the name search). Cross check any names that appear by using a social security number or EIN.

- When? Develop a policy and procedure to screen individuals and entities at the time of employment or contracting and periodically thereafter (state a frequency – for example, monthly). Follow the policy and procedure.

- Where? The LEIE is available at http://exclusions.oig.hhs.gov.

- Why? Reduce potential overpayments, CMP liability, and promote quality health care. ■

Michael W. Chase

Idaho State University Fined $400,000 for HIPAA Security Rule Violation

In August 2010, the Idaho State University notified the HHS Office for Civil Rights (the "OCR") that, after they performed routine server maintenance for their Pocatello Family Medicine Clinic, technicians failed to put the server firewall back into place. This left the protected health information on 17,500 patients exposed for at least 10 months.

Once the University discovered this exposure they conducted an investigation, notified the affected patients and reported the breach to the Office of Civil Rights. The OCR opened an investigation in November 2011 which concluded:

1. The University did not conduct an analysis of the risk to the confidentiality of ePHI as part of its security management process from April 1, 2007 until November 26, 2012;

2. The University did not adequately implement security measures sufficient to reduce the risks and vulnerabilities to a reasonable and appropriate level from April 1, 2007 until November 26, 2012; and

3. The University did not adequately implement procedures to regularly review records of information system activity to determine if any ePHI was used or disclosed in an inappropriate manner from April 1, 2007 until June 6, 2012.

In summary, OCR found that the University risk analyses and assessments of its clinics were incomplete and inadequately identified potential risks or vulnerabilities. The University also failed to assess the likelihood of potential risks occurring. Based on this finding, the OCR fined the University $400,000 and imposed a 2 year corrective action plan.

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As we have noted before, an "accurate and thorough" Risk Analysis is a core requirement of the HIPAA Security Rule (see: 45 CFR § 164.308(a)(1)(ii)(A)) . The Security Rule does not specify how frequently to perform risk analysis as part of a comprehensive risk management process. The OCR has indicated that entities may want to perform an analysis annually and are required to perform it as needed (e.g., bi-annual or every 3 years) depending on circumstances of their environment.

The Security Rule questions which covered entities and business associates should be asking themselves are:

1. Do you have an accurate and thorough, up-to-date Risk Analysis?

2. Is the Risk Analysis in writing?

3. Have you implemented proper safeguards in light of the vulnerabilities and threats identified in the Risk Analysis?

4. Have you implemented the required policies and procedures?

5. Do you have a plan to respond immediately if a security breach occurs tomorrow? ■

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OCR Launches Nationwide Compliance Review of CAH Language-Access Programs

On April 30th, the Office of Civil Rights (OCR) announced that it will begin compliance reviews to support language access programs in critical access hospitals (CAHs) as part of federal efforts to reduce health disparities. OCR reviews will focus on compliance with Title VI of the Civil Rights Act of 1964, which requires CAHs to ensure that individuals who do not speak English as their primary language and who have a limited ability to read, speak, write, or understand English can effectively participate in and benefit from hospital programs and services.

The reviews will expand OCR's 2012 ten-state pilot review of CAH compliance with Title VI nationwide. For each hospital reviewed in the pilot, OCR examined demographic data from the hospital's service area, conducted on-site visits, evaluated language access policies and procedures, interviewed staff and

community stakeholders, and secured corrective action for any compliance issues discovered. The agency provided significant technical assistance to help CAHs audit and enhance their language access services during the pilot and plans to continue to offer this assistance to hospitals moving forward.

As recipients of federal funds, CAHs must take reasonable steps to ensure meaningful access to their services and activities by individuals who may have limited English proficiency (LEP). A hospital's duty to provide language assistance to LEP individuals is a fact-dependent inquiry that balances four factors: (1) the number or proportion of LEP persons eligible to be served or likely to be encountered by the CAH; (2) the frequency with which LEP individuals come into contact with the CAH's programs; (3) the nature and importance of the program, activity, or service provided by the CAH to beneficiaries; and (4) the resources available to the CAH and the costs of interpretation or translation services.

Using this four-factor analysis, a CAH determines whether it should translate specific documents or portions of documents into the languages of various frequently-encountered LEP groups eligible to be served by the hospital or likely to be affected by the hospital's programs. This will depend on the CAH's assessment of whether specific documents are "vital" to its programs and the consequences to an LEP person if the information in question cannot be timely or accurately provided.

If a hospital identifies a need to provide language-assistance services, it has considerable flexibility in developing its plan to meet the identified needs of the LEP populations it services. The U.S. Department of Health & Human Services (HHS) explains that there is no "one size fits all" solution for compliance with Title VI, and that what constitutes "reasonable steps" for a large provider may not be reasonable vis-à-vis a smaller hospital.

Anyone who believes that he or she has been discriminated against due to race, color, or national origin by a CAH can file a complaint with OCR. HHS publishes settlement agreements resolving Title VI discrimination complaints on the OCR website: http://www.hhs.gov/ocr/civilrights/activities/examples/LEPindex.html. You can also access federal advice and technical assistance on developing and implementing language-access programs through OCR's website at http://www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/index.html. ■

Whitney C. West

Community Health Needs Assessments – Proposed Rules Issued by the IRS

Tax-exempt hospitals are required by section 501(r) of the Internal Revenue Code to perform a community health needs assessment ("CHNA") at least once every three years. Tax-exempt hospitals must both perform and complete a CHNA and formally adopt an implementation strategy based on the CHNA by the end of their first tax year that begins after March 23, 2012. This means that, depending on when a particular hospital's tax year ends, hospitals have either passed the deadline for adopting and implementing a CHNA or are in the middle of the tax year in which the CHNA requirements must be satisfied.

The IRS previously published Notice 2011-52 to provide guidance to the industry on the proper methodology to follow when performing a CHNA. Hospitals were entitled to rely upon that Notice when performing CHNAs for six (6) months following the publication of further proposed rules on CHNAs. Those proposed rules were formally published by the IRS on April 5, 2013. Thus, for CHNAs that will be completed (and implementation strategies adopted) prior to October 5, 2013, hospitals may continue to rely upon the Notice. Those CHNAs that will not be completed until after October 5, 2013 should utilize the proposed regulations for guidance.

Please see our previous article entitled "IRS Issues Guidance on the Community Health Needs Assessment" to review the highlights of Notice 2011-52.

The proposed CHNA rules closely follow the Notice. However, there are a few noticeable clarifications and differences, some of which are highlighted below:

- The proposed regulations permit multiple facilities to produce a single report so long as the facilities share the same definition of "community". Notice 2011-52 provided that parties could join forces in performing a community health needs assessment, but that separate reports needed to be produced for each hospital facility. Even in the proposed regulations, however, each hospital facility's governing body must still separately adopt the CHNA even though the CHNA reports may be identical.

- Likewise, the proposed regulations permit hospital facilities to adopt joint implementation strategies so long as (i) they adopted a joint CHNA report, (ii) the joint hospital implementation strategy clearly applies to the hospital facility in question, (iii) the implementation strategy adopted clearly identifies the hospital facility's particular role and responsibilities in the implementation strategy, and (iv) the joint implementation strategy includes a summary that helps the reader locate parts of the implementation strategy that apply to the hospital facility in question.

- The proposed regulations continue to require gathering input from those with expertise in public health and members of medically underserved, low-income, and minority populations in the community, but also permit the hospital to include written comments received on the hospital's most recently conducted CHNA. The proposed regulations also provide flexibility in gathering this information from individuals who are representatives of these populations.

- Health needs that need to be prioritized and addressed in the implementation strategy are limited to the "significant health needs" that are identified in the CHNA. The hospital is no longer required to address every health need that is identified in the assessment process in the implementation strategy. The proposed regulations continue to state that the hospital need not address each identified need, but for those needs that will not be addressed, the hospital will need to explain why it does not intend to address them.

- The IRS provided transitional relief for the adoption of the implementation strategy associated with the first CHNA. For those CHNAs that are performed during the first tax year beginning after March 23, 2012, the CHNA will be compliant so long as the implementation strategy is adopted by the board on or before the fifteenth day of the fifth calendar month following the close of the tax year. Implementation strategies for subsequent CHNAs must be adopted during the same tax year in which the CHNA is performed.

There are numerous other clarifications and changes in the proposed regulations, so those hospitals that are currently performing CHNAs but will not have them completed by October 5, 2013 should review the proposed regulations carefully and ensure that their CHNA conforms to the proposed regulations rather than Notice 2011-52.

The proposed regulations go beyond CHNAs. They also contain provisions related to the failure to satisfy 501(r) requirements. The failure to conduct a compliant CHNA will result in a $50,000 excise tax being assessed against the hospital facility each year that it remains non-compliant. However, the statute did not provide for excise taxes or intermediate sanctions for the failure to satisfy the other provisions of 501(r) (e.g., a charity care policy that fails to contain the written requirements specified in the statute, failing to limit charges for those who are eligible for charity care to not more than amounts general billed to those with insurance, taking extraordinary collection actions prior to making reasonable efforts to determine if a patient is eligible for charity care). The industry was concerned that even a minor lapse in a charity care policy, for example, would technically yield a revocation of exemption under the statute.

The proposed CHNA regulations set forth the IRS's attempt to address this issue. The proposed regulations create a three-tiered structure in analyzing a facility's shortcoming with the 501(r) provisions.

First the IRS creates a category of "minor and inadvertent omissions and errors." These errors address issues such as the failure to insert required information in hospital policies. So long as the error was minor, inadvertent, and due

to reasonable cause and the hospital facility corrects the error as promptly after discovery as reasonable given the nature of the error or omission, the hospital's tax-exempt status will not be revoked.

If the error or omission does not satisfy this first standard, a hospital's exemption may still be safe if the failure to satisfy 501(r) was neither willful nor egregious and the hospital corrects the error and makes a disclosure to the IRS. The IRS will be the final arbiter as to whether the error or omission was willful or egregious, and the facility may be subject to intermediate sanctions at the discretion of the IRS. The IRS will provide further guidance as to the notification process.

Finally, if the error or omission does not satisfy either standard, the IRS will consider the relevant facts and circumstances to determine whether the error or omission should result in the revocation of exemption as to the hospital facility in question. Some of the facts and circumstances the IRS will consider include, among others, (i) the size, scope, nature, and significance of the organization's failure; (ii) whether there is a history of failure to comply with 501(r); (iii) the reason for the compliance failure; and (iv) whether the facility, prior to the failure, had adopted practices and procedures that were designed to comply with section 501(r). If the IRS deems the failure to be egregious, it may revoke the exemption as to the organization in question (provided the organization operates only one licensed hospital).

The proposed rules confirm that a failure may be hospital specific for those tax-exempt organizations that operate more than one licensed hospital under the same corporate entity. Such an error could result in the operations of one hospital being considered unrelated business taxable income or, depending on the size of the offending hospital in relation to the entire exempt organization, could result in the entire organization losing its exempt status. The IRS confirmed that income earned by an offending facility will be taxable and reported on the Form 990-T.

Finally, the IRS previously indicated that it intended to finalize the proposed charity care regulations shortly after it issued proposed rules on the performance of CHNAs. However, with the issuance of these proposed rules, the IRS indicated that it intends to finalize all of the 501(r) regulations at the same time. This means that unless there is a change in plan, the proposed charity care regulations will continue to provide guidance as to the provision of financial assistance to patients for the foreseeable future and will not become final until the IRS has received comments on the CHNA proposed rules, reviewed those comments, and made any necessary revisions to the proposed CHNA rules. It is likely that finalized 501(r) regulations will not be issued earlier than late summer to early fall.

In the meantime, we continue to recommend that facilities subject to 501(r), including dual status governmental hospitals, adopt policies and procedures that conform to the proposed regulations. ■

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