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SCREENING OF HEALTH CARE PRACTITIONERS, EMPLOYEES, VENDORS AND CONTRACTORS

INTRODUCTION

The purpose of this memo is to provide citation to the legal authorities regulating the screening of health care practitioners, employees and vendors. This memo is not intended to serve as a legal opinion or advice, but rather to provide citation to pertinent authority addressing the issue, and it is understood that the recipient of this memo is relying solely on the advice of its own counsel regarding its compliance obligations.

Citation is provided below to the laws and regulations pertaining to:

- The Patient Protection and Affordable Care Act[1] mandate that healthcare entities have a compliance program;
- U.S. Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") exclusion authority;
- Requirement that all persons/entities excluded from one federal program be excluded from all federal programs;
- Exclusion screening requirements and OIG advocated best practices;
- Monthly licensure screening requirements;
- Requirement to check state exclusion lists;
- Requirement that providers comply with state screening laws; and
- Penalties which may be imposed for employment of excluded persons or entities.

THE ACA REQUIRES ENTITIES WHICH PARTICIPATE IN MEDICARE, MEDICAID AND CHIP TO HAVE AND FOLLOW A COMPLIANCE PROGRAM

As part of the ACA's strategy of protecting federal programs from fraud, waste, and abuse, all health care providers[2] are required to establish and maintain effective compliance programs.[3] The Secretary of Health and Human Services ("Secretary") in conjunction with the HHS-OIG is charged with establishing the core elements of such compliance programs. The HHS has yet to

[1] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (hereinafter "ACA").
[2] Providers include physicians, chiropractors, dentists, optometrists, podiatrists, psychologists, physical and occupational therapists and speech language pathologists.
[3] 42 U.S.C. § 1395cc(j)(9).

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proscribe the core elements for compliance programs.[4] However, the HHS OIG has indicated that it will rely on the U.S. Federal Sentencing Guidelines when it does so.[5]

Compliance with screening regulations and sound credentialing practices is a fundamental aspect of any sound compliance program. Thus, health care entities are required to have written policies pertaining to screening and credentialing which are consistent with regulatory requirements. Entities that fail to maintain a compliance program could be excluded from eligibility to participate in federal health care programs, even if they have not been cited for compliance violations.

THE OIG's EXCLUSION AUTHORITY

The HHS-OIG has authority to exclude individuals and entities from participating in Medicare and State health care programs under the Social Security Act ("SSA").[6] A person or entity that has been excluded is prohibited from participating in any health care program that receives federal funding (including Medicare, Medicaid, CHIP, TRICARE and Veteran's programs).[7] Under certain circumstances, including, but not limited to, conviction of program related crimes or patient abuse or felony conviction relating to health care fraud or to controlled substances, exclusion is mandatory.[8] The HHS-OIG also has discretionary authority to exclude persons for lesser offenses, including an individual's failure to repay student loans.[9]

The SSA sets minimum periods of exclusion, but also provides the HHS-OIG authority to impose longer periods.[10] Minimum exclusion periods for mandatory offenses are five years,[11] except for circumstances where an individual has been convicted on one previous occasion of one or more offenses (10 years)[12] and on two or more previous occasions of one or more mandatory offenses (permanent).[13] Minimum exclusion periods for permissive offenses run from three years to no minimum.[14] Once the exclusion period terminates, the provider is not automatically eligible to participate in federal health care programs.[15] The excluded provider may apply for reinstatement by submitting a written request for reinstatement that includes documentation demonstrating that certain standards have been met.[16] After the application for

[4] 42 U.S.C. § 1395cc(j)(9)(B).
[5] 76 Fed. Reg. 5,862, 5,941-43 (Feb. 2, 2011).
[6] 42 U.S.C. § 1320a-7.
[7] 42 U.S.C. § 1320a-7(a).
[8] *Id.*
[9] 42 U.S.C. § 1320a-7(b).
[10] 42 U.S.C. § 1320a-7(c).
[11] 42 U.S.C. § 1320a-7(c)(3)(B).
[12] 42 U.S.C. § 1320a-7(c)(3)(G)(i).
[13] 42 U.S.C. § 1320a-7(c)(3)(G)(ii).
[14] 42 U.S.C. § 1320a-7(c)(3)(D)-(E).
[15] 42 C.F.R. § 1001.3001(a)(1).
[16] 42 C.F.R. § 1001.3001(a)(2).

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reinstatement is submitted, the HHS-OIG must determine whether or not to grant authorization to reinstate.[17]

INDIVIDUALS AND ENTITIES WHICH HAVE BEEN EXCLUDED FROM ANY FEDERAL AGENCY PROGRAM ARE EXCLUDED FROM ALL HEALTH CARE PROGRAMS

Under the Federal Acquisition Regulations[18] and several Executive Orders, if an individual or entity is excluded or debarred from participating in any federal agency program, the individual or entity is excluded from all other federal agency programs, including Medicare, Medicaid and all other health care programs.

Executive Order 12,549 established a government-wide system of non-procurement, suspension and debarment and directed the creation of the Interagency Committee on Debarment and Suspension.[19] The Order directs Executive departments and agencies to:

- participate in activities involving Federal financial and nonfinancial assistance and benefits,[20]
- issue regulations with government-wide criteria and minimum due process procedures when debarring or suspending participants,[21] and
- enter debarred and suspended participants' identifying information on the General Services Administration list of excluded persons, now known as Excluded Parties List System (EPLS). Information placed on the EPLS is the responsibility of the agency issuing the suspension or debarment.[22]

Subsequently, Executive Order 12,689 mandated that debarments, suspensions or exclusions are to have government-wide effect.[23] The Order states in part:

> "the debarment, suspension, or other exclusion of a participant in a procurement activity under the Federal Acquisition Regulation, or in a nonprocurement activity under regulations issued pursuant to Executive Order No. 12549, shall have governmentwide effect. No agency shall allow a party to participate in any procurement or nonprocurement activity if any agency has debarred, suspended,

[17] 42 C.F.R. § 1001.3002.
[18] 48 C.F.R. Ch. 1.
[19] 51 Fed. Reg. 6,370 (Feb. 21, 1986).
[20] *Id.* at section 1(a).
[21] *Id.* at section 6.
[22] *Id.* at section 2(c).
[23] 54 Fed. Reg. 34,131 (Aug. 18, 1989).

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> or otherwise excluded (to the extent specified in the exclusion agreement) that party from participation in a procurement or nonprocurement activity."[24]

Legislation implementing the Order, The Federal Acquisition and Streamlining Act of 1994, provides:

> "REQUIREMENT FOR REGULATIONS- Regulations shall be issued providing that provisions for the debarment, suspension, or other exclusion of a participant in a procurement activity under the Federal Acquisition Regulation, or in a nonprocurement activity under regulations issued pursuant to Executive Order No. 12549, shall have government-wide effect. No agency shall allow a party to participate in any procurement or nonprocurement activity if any agency has debarred, suspended, or otherwise excluded (to the extent specified in the exclusion agreement) that party from participation in a procurement or nonprocurement activity."[25]

General rules pertaining to debarment and suspension are set forth in the Federal Acquisition Regulations, which reiterates the government-wide reciprocal effect of a debarment or suspension, and provides for the preclusion of the awarding of contracts to any debarred or suspended contractor.[26]

Subsequent Executive Orders prohibit transactions with terrorists.[27] Individuals and entities designated by the U.S. Government pursuant to these Executive Orders have been compiled and consolidated on an extensive list maintained by the Department of Treasury's Office of Foreign Assets Control ("OFAC"). The list is referred to as the Specially Designated Nationals List.

EXLUSION SCREENING REQUIREMENTS AND BEST PRACTICES

Screening Frequency

Providers must screen practitioners and employees for exclusions at hire or privileging.[28] After hire or contracting, Centers for Medicare & Medicaid Services ("CMS") and the HHS-OIG have repeatedly stated that exclusion screening must be performed "periodically," but there is no law which defines the term.[29]

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[24] *Id.* at section 2.
[25] Pub. L. No. 103-355, § 2455(a), 108 Stat. 3,243, 3,327 (1994), *see* 31 U.S.C. § 6101 note.
[26] 48 C.F.R. §§ 9.400 – 9.409.
[27] *See* Exec. Order No. 12,947 (60 Fed. Reg. 5,079 (Jan. 25, 1995)); Exec. Order No. 13,099 (63 Fed. Reg. 45,167 (Aug. 25, 1998)); and Exec. Order No. 13,224 (66 Fed. Reg. 49,079 (Sept. 25, 2001)).
[28] Letter from Herb B. Kuhn, Deputy Administrator, Acting Director, Center for Medicaid and State Operations, to State Medicaid Director (Jan. 16, 2009) (SMDL#09-001), available at http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD011609.pdf.
[29] *Id.*

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Thus, there has been a lack of certainty regarding how often screening must be done and who must be screened. In May, 2013, the HHS-OIG released a Special Advisory Bulletin ("Bulletin") that was intended to clarify these issues.[30] The Bulletin, which states that it supersedes prior guidance, covers:

- The statutory framework and history of exclusion law;
- Best practices regarding when and how exclusion screening should be performed; and
- The impact of exclusion and provider[31] liability for employing or contracting with excluded persons or entities.

The Bulletin states that it "provides guidance to the health care industry on the scope and frequency of screening employees and contractors to determine whether they are excluded persons."[32] The HHS-OIG does not provide bright-line rules, but rather continues its history of focusing on the potential consequences of complying with its "best practices."

With respect to the frequency of screening, the Bulletin states that providers should check the List of Excluded Individuals/Entities ("LEIE") prior to employing or contracting with persons and "periodically" check the LEIE to determine the exclusion status of current employees and contractors.[33] OIG notes that there is no "statutory or regulatory requirement to check the LEIE, providers may decide how frequently to check the LEIE."[34] Although prior guidance have used the term "periodically" for more than a decade, it has never been defined and it is not defined in the Bulletin. However, the HHS-OIG recommends monthly screening of employees and contractors in order to minimize potential overpayment and civil monetary penalty liability.[35]

Monthly exclusion screening is consistent with the obligations of Medicaid agencies. Under the ACA, Medicaid agencies must check the LEIE and EPLS for exclusions. More specifically, under the provider screening and enrollment regulation:

> "The State Medicaid agency must do all of the following:
>
> (a) Confirm the identity and determine the exclusion status of providers and any person with an ownership or control interest or who is an agent or managing employee of the provider through routine checks of Federal databases.

[30] "Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs" (May 8, 2013) is available at https://oig.hhs.gov/exclusions/files/sab-05092013.pdf.
[31] The term "provider" is used broadly in the Bulletin to include all providers, suppliers, manufacturers, and any other individual or entity, including a drug plan sponsor or managed care entity that directly or indirectly furnishes, arranges, or pays for items or services. *Id.* at pg. 2, fn 5.
[32] *Id.* at pg. 1.
[33] *Id.* at pg. 15.
[34] *Id.*
[35] *Id.*

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> (b) Check the Social Security Administration's Death Master File, the National Plan and Provider Enumeration System (NPPES), the List of Excluded Individuals/Entities (LEIE), the Excluded Parties List System (EPLS), and any such other databases as the Secretary may prescribe.
>
> (c)(1) Consult appropriate databases to confirm identity upon enrollment and reenrollment; and
>
> (2) Check the LEIE and EPLS no less frequently than monthly."[36]

The ACA requires State Medicaid agencies to terminate the participation of any individual or entity if such individual or entity has been terminated under Medicare or any other State Medicaid plan.[37]

How Screening Should Be Done

The HHS-OIG recommends that exclusion screening should be performed through the LEIE because it is updated monthly, provides more details about the basis for exclusion than the General Services Administration's ("GSA") System for Award Management ("SAM"), and is maintained by the HHS-OIG and therefore HHS-OIG staff can respond to questions and requests for verifications. The HHS-OIG notes that there is no requirement to utilize LEIE.[38]

Who Should Be Screened

In order to determine who must be screened, the HHS-OIG recommends that the following test be used:

> Is the service or item provided by the employee, practitioner, or vendor payable by a Federal health care program, either directly or indirectly, or in whole or in part?[39]

Under this test, a provider that receives federal funding may only employ an excluded individual where: 1) the provider can pay the employee exclusively with private funds; and 2) the employee does not provide any services which relate to federal program patients. In order to satisfy the

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[36] 42 C.F.R. § 455.436(c)(2). Please note that in July of 2012, the Excluded Parties List System was migrated to the System for Award Management.
[37] 42 U.S.C. § 1396a(a)(39); *see also* CMS Informational Bulletin CPI-B 12-02 (Jan. 20, 2012), available at http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-01-20-12.pdf.
[38] *See* "Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs" (May 8, 2013).
[39] *Id.* at pgs. 15-16.

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former, the provider would need to have a segregated accounting system, separating revenues received from private sources from revenues received from federal or Medicaid sources.[40]

The government ban on payment for items or services furnished by an excluded individual extends beyond direct patient care. It includes persons that provide administrative, managerial, technical or other services. To provide guidance regarding who must be screened, the Bulletin provides numerous examples of persons and vendors which should be screened.

Examples include:

- Services performed by excluded individuals who prepare surgical trays or review treatment plans, regardless of whether such services are separately billable or are included in a bundled payment.
- Excluded pharmacists who input prescription information for billing or who are involved in any way in filling prescriptions for drugs billed to a federal health care program.
- Ambulance drivers or dispatchers whose services are billed to federal programs.
- Persons that have executive or leadership roles (e.g., CEO, CFO, GC, CTO, HR director).
- Provided other types of administrative or management services (including IT services, strategic planning, billing, accounting, staff training, unless such services are wholly unrelated to Federal programs).
- Services furnished at the direction or prescription of an excluded person if that person knows or should know of the exclusion. Thus, providers that furnish such services on the basis of orders or prescriptions, such as labs, imaging centers, DMES, and pharmacies will not get paid if the ordering physician was excluded.[41]

"To avoid liability, providers should ensure, at the point of service, that the ordering or prescribing physician is not excluded."[42]

CMS also addressed the requirement that providers screen "their own employees and contractors for excluded persons."[43] CMS reiterated that federal health care programs are prohibited from paying for services, etc. "furnished, ordered, or proscribed by excluded individuals or entities."[44]

The memo states that the ban applies to, among other things:

- "payment for administrative and management services not directly related to patient care, but that are a necessary component of providing items and services to

[40] *See* "The Effect of Exclusion From Participation in Federal Health Care Programs," Special Advisory Bulletin (Sept. 1999) available at https://oig.hhs.gov/exclusions/effects_of_exclusion.asp.
[41] *Id.*
[42] *See* "Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs" (May 8, 2013), at pg. 8.
[43] Letter from Herb B. Kuhn, Deputy Administrator, Acting Director, Center for Medicaid and State Operations, to State Medicaid Director (Jan. 16, 2009) (SMDL#09-001), at pg. 1.
[44] *Id.*

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Medicaid recipients, when those payments are reported on a cost report or are otherwise payable by the Medicaid program; and

- payment to cover an excluded individual's salary, expenses or fringe benefits, regardless of whether they provide direct patient care, when those payments are reported on a cost report or are otherwise payable by the Medicaid program."[45]

The ACA restates guidelines previously published in the HHS-OIG's 1999 Special Advisory Bulletin. The Bulletin states that "any items and services furnished at the medical direction or prescription of an excluded physician are not reimbursable when the individual or entity furnishing the services either knows or should know of the exclusion."[46] Accordingly, as early as 1999, the OIG made it clear that a provider does not need to have actual knowledge that it is employing an excluded practitioner.

With respect to the scope of the prohibition against making payments, the Bulletin states, in part:

> "The prohibition against Federal program payment for items or services furnished by excluded individuals or entities also extends to payment for administrative and management services not directly related to patient care, but that are a necessary component of providing items and services to Federal program beneficiaries. This prohibition continues to apply to an individual even if he or she changes from one health care profession to another while excluded. In addition, no Federal program payment may be made to cover an excluded individual's salary, expenses or fringe benefits, regardless of whether they provide direct patient care."
>
> "Thus, a provider or entity that receives Federal health care funding may only employ an excluded individual in limited situations. Those situations would include instances where the provider is both able to pay the individual exclusively with private funds or from other non-federal funding sources, and where the services furnished by the excluded individual relate solely to non-federal program patients.
>
> In many instances, the practical effect of an OIG exclusion is to preclude employment of an excluded individual in any capacity by a health care provider that receives reimbursement, indirectly or directly, from any Federal health care program."[47]

When determining who must be screened, the common issue is often whether the purpose and costs of employing a specified person or vendor would be so attenuated from any federal health care program that employment of an excluded person would be permissible. (Does a hospital

[45] *Id.* at pg. 2.
[46] *See* "The Effect of Exclusion From Participation in Federal Health Care Programs," Special Advisory Bulletin (Sept. 1999).
[47] *Id.*

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need to screen outside financial consultants and contractors that make physical improvements to the facility, or its landscaping service?) There is no bright-line rule, and analysis will be based on the facts.[48]

REQUIREMENT TO REVIEW STATE LICENSING BOARD DATA ON A MONTHLY BASIS

The obligation of providers and suppliers furnishing services under Medicare and Medicaid to check State licensure lists is set forth in a final rule issued by the HHS in 2011, which states in part:

> "(W)e require that Medicare contractors review State licensing board data on a monthly basis to determine if providers and suppliers remain in compliance with State licensure requirements."[49]

Whether this regulation has the force of a statute was addressed by Congress. The SSA provides general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.[50] According to the HHS final rule "[p]roviders and suppliers furnishing services must comply with the Medicare requirements stipulated in the Act and in our regulations."[51]

REQUIREMENT TO CHECK STATE EXCLUSION LISTS

A state may exclude a provider from a state program for any reason that the HHS-OIG could exclude a provider from a federal health care program.[52] The states are required to promptly notify the HHS-OIG of any action taken by a state to limit the ability of an individual or entity to participate in its program,[53] as well as other state agencies, licensing boards, the public and other appropriate state and local agencies having responsibility for the licensing or certification of the excluded person.[54]

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[48] For an example in which the OIG found an employee's relationship so remote that the employer would not be liable for employing an excluded person *see* OIG Advisory Opinion No. 03-01 (Jan. 13, 2001) available at http://oig.hhs.gov/fraud/docs/advisoryopinions/2003/ao0301.pdf. (OIG stated that it would be permissible for a data and software company serving the health care sector to employ an excluded physician because physician would have no association with the division of the company that provides services that are directly or indirectly reimbursable by a federal health care program and he would have no involvement with the division of the company that provided reimbursable services.)

[49] 76 Fed. Reg. 5,862, 5,865-66 (Feb. 2, 2011).

[50] *See* 42 U.S.C. § 1302 and 42 U.S.C. § 1395hh.

[51] 76 Fed. Reg. 5,862, 5,864 (Feb. 2, 2011).

[52] 42 U.S.C. § 1396a(p)(1).

[53] 42 C.F.R. § 1002.3(b)(3).

[54] 42 C.F.R. § 1001.2005.

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More than one-half of the states currently maintain their own exclusion lists under HHS OIG regulations. Providers are obligated to search their state list whenever they search the LEIE.[55]

REQUIREMENT TO COMPLY WITH STATE SCREENING REGULATIONS

Federal authority does not restrict the States' right to implement more stringent screening requirements or exclusion remedies.[56] Many state Medicaid agencies have their own regulations regarding screening of providers and contractors, some of which require more than adherence to federal law.

For example, in New Jersey, providers and HMOs are required to verify if current or prospective employees (regular or temporary), contractors, or subcontractors who directly or indirectly will be furnishing, ordering, directing, managing or prescribing items or services in whole or in part are not excluded, unlicensed or uncertified by searching the following databases on a **monthly** basis:

- Federal exclusions database (mandatory);
- N.J. Treasurer's exclusions database (mandatory);
- N.J. Division of Consumer Affairs licensure databases (mandatory);
- N.J. Department of Health and Senior Services licensure database (mandatory); and
- Certified nurse aide and personal care assistant registry (mandatory, if applicable).[57]

CONSEQUENCES OF EMPLOYING EXCLUDED AND/OR UNLICENSED PERSONS

In the event that a provider entity employs an excluded person, statutory penalties and remedies which may be imposed include the following:

Civil Monetary Penalties for Employing Excluded Providers

Civil Monetary Penalties ("CMPs") may be imposed against entities that employ excluded individuals.[58] The CMP statute[59] calls for the imposition of penalties against any person or entity which presents a claim to a federal health care program and which:

> "arranges or contracts (by employment or otherwise) with an individual or entity that the person knows or should know is excluded from participation in a Federal health care program (as defined in section [1320a–7b (f) of this title]), for the

[55] *See* letter from Herb B. Kuhn, Deputy Administrator, Acting Director, Center for Medicaid and State Operations, to State Medicaid Director (Jan. 16, 2009) (SMDL#09-001).
[56] 42 C.F.R. § 455.452.
[57] *Excluded, Unlicensed or Uncertified Individuals or Entities* (N.J. Dept. of Human Services Newsletter) Vol. 20 No. 22, Oct. 2010.
[58] 42 U.S.C. § 1320a-7a(a)(6); 42 C.F.R. § 1003.102(a)(2).
[59] 42 U.S.C. § 1320a-7a.

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> provision of items or services for which payment may be made under such a program."[60]

The HHS-OIG may impose penalties of up to $10,000 for each item or service furnished by an excluded person plus three times the amount sought from the government.[61]

The HHS-OIG provides information regarding CMPs imposed for false and fraudulent claims, including those premised on the employment of excluded persons/entities. This information can be found in the False and Fraudulent Claims Archive.[62]

Civil Monetary Penalties for Employing Unlicensed Providers

There is a specific provision in the CMP statute dealing with physicians. More specifically, an entity is liable for penalties if it submits a claim for physician services, if the entity knew or should have known that the person that provided the services:

> "(i) was not licensed as a physician,
> (ii) was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing), or
> (iii) represented to the patient at the time the service was furnished that the physician was certified in a medical specialty by a medical specialty board when the individual was not so certified."[63]

Non-Payment

When the OIG has excluded a provider, federal health care programs are generally prohibited from making payment for any items or services furnished, ordered, or prescribed by the excluded provider.[64]

Exclusion of Managed Care Organizations from Medicaid

Under the SSA, States are required to exclude from Medicaid any managed care organization that:

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[60] 42 U.S.C. § 1320a-7a(a)(6); *see also* 42 U.S.C. § 1320a-7a(a)(1)(D).

[61] Hypothetical: Assume XYZ Pharmacy employs a pharmacist for a one month period during which he was excluded. During that month, the pharmacist fills a total of 1,848 prescriptions (12 per hour X 7 hours per day X 22 days). 50% of the prescriptions (924) are billed to Medicaid or a federal health care program in the total amount of $69,300 ($75 per prescription). Potential penalties: $69,300 – non-payment; $207,900 – treble damages; $9,240,000 – penalties. Total amount of penalties which could be imposed: $9,517,200.

[62] Available at https://oig.hhs.gov/reports-and publications/archives/enforcement/criminal/criminal_archive_2016.asp.

[63] 42 U.S.C. § 1320a-7a(a)(1)(C).

[64] 42 C.F.R. § 1001.1901.

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> "employs or contracts with any individual or entity that is excluded from participation under this title under [42 U.S.C. § 132a-7 or 1320a-7a] for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services."[65]

Possible Criminal Prosecution of Executive Decision Makers

The HHS-OIG has authority to prosecute felony actions against corporate decision makers for health care fraud and it has been doing so aggressively the past couple of years in conjunction with the Department of Justice. To date, we are unaware of any such action premised on the employment of excluded persons. However, this penalty is available to the HHS-OIG and could be used in egregious circumstances.

* * * * *

We hope that you find the above information useful. We reiterate that this memo is not intended to, and should not be construed as, providing legal advice or a legal opinion and that you should rely solely upon the advice of your own legal counsel with respect to the issues addressed in this memo.

[65] 42 U.S.C. § 1396a(p)(2)(C).

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