

# UPDATED

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## **Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs**

**Issued May 8, 2013**



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**



# **Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs**

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This updated Special Advisory Bulletin describes the scope and effect of the legal prohibition on payment by Federal health care programs for items or services furnished (1) by an excluded person or (2) at the medical direction or on the prescription of an excluded person. For purposes of Office of Inspector General (OIG) exclusion, payment by a Federal health care program includes amounts based on a cost report, fee schedule, prospective payment system, capitated rate, or other payment methodology. It describes how exclusions can be violated and the administrative sanctions OIG can pursue against those who have violated an exclusion. The updated Bulletin provides guidance to the health care industry on the scope and frequency of screening employees and contractors to determine whether they are excluded persons.

## **INTRODUCTION**

OIG was established in the U.S. Department of Health and Human Services (Department) to identify and eliminate fraud, waste, and abuse in the Department's programs and to promote efficiency and economy in Departmental operations. OIG carries out this mission through a nationwide program of audits, inspections, and investigations. In addition, the Secretary has delegated authority to OIG to exclude from participation in

Medicare, Medicaid, and other Federal health care programs<sup>1</sup> persons<sup>2</sup> that have engaged in fraud or abuse and to impose civil money penalties (CMPs) for certain misconduct related to Federal health care programs.<sup>3</sup>

OIG originally published a Special Advisory Bulletin in September 1999 (1999 Bulletin) on the effect of exclusion from participation in Federal health care programs.<sup>4</sup> The publication of the 1999 Bulletin coincided with the beginning of a significant and ongoing OIG initiative to ensure compliance with and enforcement of exclusions. The 1999 Bulletin provided guidance to excluded persons as to the scope and effect of their exclusions and the activities that might result in a violation of their exclusions. The 1999 Bulletin also provided guidance to providers<sup>5</sup> that might arrange with, contract with, or employ an excluded person regarding (1) what the scope of the prohibition on employment or contracting is, (2) when the provider might be subject to CMPs for violating this prohibition, and (3) how to determine whether a potential employee or contractor is excluded.

The health care industry and OIG have now had more than a decade of experience with the questions that arise in determining the effect of an

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<sup>1</sup> A Federal health care program is defined as any plan or program that provides health benefits, whether directly, through insurance, or otherwise, and that is funded directly, in whole or in part, by the U.S. Government or a State health care program (except for the Federal Employees Health Benefits Program) (section 1128B(f) of the Social Security Act (the Act)). Among the most significant Federal health care programs are Medicare, Medicaid, TRICARE, and the veterans' programs.

<sup>2</sup> The exclusions statute applies to "individuals and entities." We use the term "person" throughout this document to encompass all individuals and entities.

<sup>3</sup> See the Act §§ 1128, 1128A, and 1156.

<sup>4</sup> See 64 Fed. Reg. 52791, September 30, 1999.

<sup>5</sup> The term "provider" is used broadly throughout this guidance to include 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.

exclusion across the broad spectrum of items and services that are furnished, directly or indirectly, within the health care industry and payable by Federal health care programs. The 1999 Bulletin has been the primary source of published guidance from OIG in this area and has proven to be important both to excluded persons and to efforts by providers to ensure compliance with the restrictions on employing or contracting with excluded individuals or entities.

Since the 1999 Bulletin, we have received many questions about exclusions, including the following:

- May an excluded person provide an item or a service that a health care provider needs but that is not for direct patient care or billing? Is a provider that employs or contracts with an excluded person to provide such item or service subject to CMP liability?
- What is the scope of the obligation to screen current and potential employees and contractors against OIG's List of Excluded Individuals and Entities (LEIE) to determine whether they are excluded? How frequently should providers screen against the LEIE? How far downstream do they need to screen (e.g., do they have an obligation to screen the employees of contractors and subcontractors in addition to screening contractors)?
- How should a provider disclose to OIG that it has employed or contracted with an excluded person?
- What is the distinction between the information that appears on the LEIE and the information that appears on the General Services Administration's (GSA) System for Award Management (SAM) and other systems that report sanctions or adverse actions taken with

respect to health care practitioners (e.g., the National Practitioner Data Bank (NPDB))?<sup>6</sup>

We address these and other issues in this updated Bulletin. In developing this Bulletin, we considered, among other things, the public comments received in response to a solicitation notice published in the Federal Register, our experience resolving numerous self-disclosure cases, and questions we have received.<sup>7</sup> This updated Bulletin replaces and supersedes the 1999 Bulletin.

## **STATUTORY BACKGROUND**

In 1977, in the Medicare-Medicaid Anti-Fraud and Abuse Amendments, Public Law 95-142 (now codified at section 1128 of the Act), Congress first mandated the exclusion of physicians and other practitioners convicted of program-related crimes from participation in Medicare and Medicaid. This was followed in 1981 with enactment of the Civil Monetary Penalties Law (CMPL), Public Law 97-35 (codified at section 1128A of the Act), to further address health care fraud and abuse. The CMPL authorizes the Department and OIG to impose CMPs, assessments, and program exclusions against any person that submits false or fraudulent or certain other types of improper claims for Medicare or Medicaid payment. Claims submitted by an excluded person for items or services furnished during the person's exclusion violate the CMPL.

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<sup>6</sup> In July 2012, GSA migrated its Excluded Parties List System (EPLS) and other systems to the new SAM. SAM is a comprehensive database that Federal agencies can use to determine the eligibility of individuals or entities to participate in their programs.

<sup>7</sup> 75 Fed. Reg. 69452, November 12, 2010.

To enhance OIG's ability to protect the Medicare and Medicaid programs and beneficiaries, the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, expanded and revised OIG's administrative sanction authorities by, among other things, establishing certain additional mandatory and discretionary exclusions for various types of misconduct.

The enactment of the Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191, in 1996 and the Balanced Budget Act (BBA) of 1997, Public Law 105-33, further expanded OIG's sanction authorities. These statutes extended the application and scope of the current CMP and exclusion authorities beyond programs funded by the Department to all "Federal health care programs." BBA also authorized a new CMP authority to be imposed against health care providers or entities that employ or enter into contracts with an excluded person to provide items or services for which payment may be made under a Federal health care program.

Since the publication of the 1999 Bulletin, various statutory amendments have strengthened and expanded OIG's authority to exclude individuals and entities from the Federal health care programs. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care Education Reconciliation Act of 2010 (ACA), expanded OIG's exclusion waiver authority. The ACA also modified and expanded OIG's permissive exclusion authorities and amended the CMPL by adding a new provision that subjects an excluded person to liability if the person orders or prescribes an item or a service while excluded and knows or should know that a claim for the item or service may be made to a Federal health care program.

## **EXCLUSION FROM FEDERAL HEALTH CARE PROGRAMS**

The effect of an OIG exclusion is that no Federal health care program payment may be made for any items or services furnished (1) by an excluded person or (2) at the medical direction or on the prescription of an excluded person.<sup>8</sup> The exclusion and the payment prohibition continue to apply to an individual even if he or she changes from one health care profession to another while excluded.<sup>9</sup> This payment prohibition applies to all methods of Federal health care program payment, whether from itemized claims, cost reports, fee schedules, capitated payments, a prospective payment system or other bundled payment, or other payment system and applies even if the payment is made to a State agency or a person that is not excluded. For example, no payment may be made to a hospital for the items or services furnished by an excluded nurse to Federal health care program beneficiaries, even if the nurse's services are not separately billed and are paid for as part of a Medicare diagnosis-related group payment received by the hospital. Also, the excluded nurse would be in violation of her exclusion for causing a claim to be submitted by the hospital for items or services the nurse furnished while excluded.

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<sup>8</sup> An excluded provider may refer a patient to a non-excluded provider if the excluded provider does not furnish, order, or prescribe any services for the referred patient, and the non-excluded provider treats the patient and independently bills Federal health care programs for the items or services that he or she provides. Covered items or services furnished by a non-excluded provider to a Federal health care program beneficiary are payable, even when an excluded provider referred the patient.

<sup>9</sup> For example, the prohibition against Federal health care program payment for items and services would continue to apply to a person who was excluded while a pharmacist even after the person earns his or her medical degree and becomes a licensed physician.

The prohibition on Federal health care program payment for items or services furnished by an excluded individual includes items and services beyond direct patient care. For instance, the prohibition applies to services performed by excluded individuals who work for or under an arrangement with a hospital, nursing home, home health agency, or managed care entity when such services are related to, for example, preparation of surgical trays or review of treatment plans, regardless of whether such services are separately billable or are included in a bundled payment. Another example is services performed by excluded pharmacists or other excluded individuals who input prescription information for pharmacy billing or who are involved in any way in filling prescriptions for drugs that are billed to a Federal health care program. Also, excluded individuals are prohibited from providing transportation services that are paid for by a Federal health care program, such as those provided by ambulance drivers or ambulance company dispatchers.

Excluded persons are prohibited from furnishing administrative and management services that are payable by the Federal health care programs. This prohibition applies even if the administrative and management services are not separately billable. For example, an excluded individual may not serve in an executive or leadership role (e.g., chief executive officer, chief financial officer, general counsel, director of health information management, director of human resources, physician practice office manager, etc.) at a provider that furnishes items or services payable by Federal health care programs. Also, an excluded individual may not provide other types of administrative and management services, such as health information technology services and support, strategic planning, billing and accounting, staff training, and human resources, unless wholly unrelated to Federal health care programs.



In addition, any items and services furnished at the medical direction or on the prescription of an excluded person are not payable when the person furnishing the items or services either knows or should know of the exclusion. This prohibition applies even when the Federal payment itself is made to a State agency or a provider that is not excluded. Many providers that furnish items and services on the basis of orders or prescriptions, such as laboratories, imaging centers, durable medical equipment suppliers, and pharmacies, have asked whether they could be subject to liability if they furnish items or services to a Federal program beneficiary on the basis of an order or a prescription that was written by an excluded physician. Payment for such items or services is prohibited.<sup>10</sup> To avoid liability, providers should ensure, at the point of service, that the ordering or prescribing physician is not excluded.<sup>11</sup>

## **VIOLATION OF OIG EXCLUSION BY AN EXCLUDED PERSON**

An excluded person violates the exclusion if the person furnishes to Federal health care program beneficiaries items or services for which Federal health care program payment is sought. An excluded person that submits a claim

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<sup>10</sup> See Act § 1862(e)(1)(B). Some excluded practitioners will have valid licenses or Drug Enforcement Agency (DEA) numbers. Therefore, it is important not to assume that because a prescription contains a valid license number or DEA number, the practitioner is not excluded.

<sup>11</sup> In some cases, pharmacies and laboratories rely on Medicare Part D plans and/or State agencies to ensure that prescribers are not excluded through, for example, computer system edits. These alternative screening mechanisms may effectively identify excluded individuals and prevent the pharmacies or laboratories from submitting claims for services ordered or prescribed by excluded individuals. However, pharmacies and laboratories that rely on a third party to determine whether prescribers are excluded should be aware that they may be responsible for overpayments and CMPs relating to items or services that have been ordered or prescribed by excluded individuals.

for payment to a Federal health care program, or causes such a claim to be submitted, may be subject to a CMP of \$10,000 for each claimed item or service furnished during the period that the person was excluded.<sup>12</sup> The person may also be subject to an assessment of up to three times the amount claimed for each item or service. In addition, violation of an exclusion is grounds for OIG to deny reinstatement to Federal health care programs.<sup>13</sup>

Such exclusion violations may lead to criminal prosecutions or civil actions in addition to the CMPs for violation of OIG exclusion. An excluded person that knowingly conceals or fails to disclose any action affecting the ability to receive any benefit or payment with the intent to fraudulently receive such benefit or payment may be subject to criminal liability.<sup>14</sup> Other criminal statutes may also apply to such violations. An excluded person may be civilly liable under the False Claims Act for knowingly presenting or causing to be presented a false or fraudulent claim for payment.<sup>15</sup>

Moreover, persons that order or prescribe items or services while excluded are subject to CMP liability when the excluded person knows or should know that a claim for the item or service may be made to a Federal health care program.<sup>16</sup>

Although an exclusion does not directly prohibit the excluded person from owning a provider that participates in Federal health care programs, there are several risks to such ownership. OIG may exclude the provider if certain

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<sup>12</sup> See section 1128A(a)(1)(D) of the Act.

<sup>13</sup> See 42 CFR § 1001.3002.

<sup>14</sup> See section 1128B(a)(3) of the Act.

<sup>15</sup> See 31 U.S.C. §§ 3729-3733.

<sup>16</sup> See section 1128A(a)(8) of the Act.

circumstances regarding the ownership are present.<sup>17</sup> Although this authority to exclude is not mandatory and OIG exercises it at its discretion, any provider owned in part (5 percent or more) by an excluded person is potentially subject to exclusion. In addition, an excluded individual may be subject to CMPL liability if he or she has an ownership or control interest in a provider participating in Medicare or State health care programs or if he or she is an officer or a managing employee of such an entity.<sup>18</sup> Further, the provider may not seek Federal health care program payment for any services, including the administrative and management services described above, furnished by the excluded owner. As a practical matter, this means that an excluded person may own a provider, but may not provide any items or services, including administrative and management services, that are payable by Federal health care programs. If an excluded owner does, for example, participate in billing activities or management of the business, both the owner and the provider will risk CMPL liability.

## **CMP LIABILITY FOR EMPLOYING OR CONTRACTING WITH AN EXCLUDED PERSON**

BBA authorized the imposition of CMPs against providers that employ or enter into contracts with excluded persons to provide items or services payable by Federal health care programs.<sup>19</sup> This authority parallels the CMP for health maintenance organizations that employ or contract with excluded individuals.<sup>20</sup>

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<sup>17</sup> See section 1128(b)(8) of the Act.

<sup>18</sup> See section 1128A(a)(4) of the Act; 42 CFR § 1003.102(a)(12).

<sup>19</sup> See section 1128A(a)(6) of the Act; 42 CFR § 1003.102(a)(2).

<sup>20</sup> See section 1857(g)(1)(G) of the Act.

If a health care provider arranges or contracts (by employment or otherwise) with a person that the provider knows or should know is excluded by OIG, the provider may be subject to CMP liability if the excluded person provides services payable, directly or indirectly, by a Federal health care program. OIG may impose CMPs of up to \$10,000 for each item or service furnished by the excluded person for which Federal program payment is sought, as well as an assessment of up to three times the amount claimed, and program exclusion.

At least since 1999, providers have been able to use the LEIE, which is available on OIG's Web site (and discussed in more detail below), to determine whether a person is excluded. In the 1999 Bulletin, we alerted providers about the availability of the LEIE to determine whether individuals and entities were excluded.

A provider could be subject to CMP liability if an excluded person participates in any way in the furnishing of items or services that are payable by a Federal health care program. CMP liability would apply to the furnishing of all of the categories of items or services that are violations of an OIG exclusion, including direct patient care, indirect patient care, administrative and management services, and items or services furnished at the medical direction or on the prescription of an excluded person when the person furnishing the services either knows or should know of the exclusion. CMP liability could result if the provider's claim to the Federal health care program includes any items or services furnished by an excluded person, even if the excluded person does not receive payments from the provider for his or her services (e.g., a non-employed excluded physician who is a member of a hospital's medical staff or an excluded health care professional who works at a hospital or nursing home as a volunteer). An excluded

person may not provide services that are payable by Federal health care programs, regardless of whether the person is an employee, a contractor, or a volunteer or has any other relationship with the provider. For example, if a hospital contracts with a staffing agency for temporary or per diem nurses, the hospital will be subject to overpayment liability and may be subject to CMP liability if an excluded nurse from that staffing agency furnishes items or services to Federal health care program beneficiaries.<sup>21</sup>

We offer the following guidance regarding the circumstances under which an excluded person may be employed by, or contract with, a provider that receives payments from Federal health care programs.<sup>22</sup> First, if Federal health care programs do not pay, directly or indirectly, for the items or services being provided by the excluded individual, then a provider that participates in Federal health care programs may employ or contract with an excluded person to provide such items or services. Second, a provider that employs or contracts with an excluded person to furnish items or services solely to non-Federal health care program beneficiaries would not be subject to CMP liability. A provider need not maintain a separate account from which to pay the excluded person, as long as no claims are submitted to or payment is received from Federal health care programs for items or services that the excluded person provides and such items or services relate solely to non-Federal health care program patients.

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<sup>21</sup> The hospital may reduce or eliminate its CMP liability if the hospital is able to demonstrate that it reasonably relied on the staffing agency to perform a check of the LEIE for the nurses furnished by the staffing agency (e.g., the staffing agency agreed by contract to perform the screening of the LEIE and the hospital exercised due diligence in ensuring that the staffing agency was meeting its contractual obligation.)

<sup>22</sup> This guidance applies only with respect to assisting providers in determining whether they are in compliance with the Act.

Thus, a provider that receives Federal health care program payments may employ or contract with an excluded person only in limited situations. Providers that identify potential CMP liability on the basis of the employment of, contracting with, or arranging with an excluded person may use OIG's Provider Self-Disclosure Protocol (SDP) to disclose and resolve the potential CMP liability.<sup>23</sup>

## **HOW TO DETERMINE WHETHER A PERSON IS EXCLUDED**

OIG maintains the LEIE on the OIG Web site (<http://oig.hhs.gov/exclusions>), which contains OIG program exclusion information.

- *List of Excluded Individuals and Entities*

The Exclusions Web site and the LEIE have undergone extensive updates and revisions in the past several years. The LEIE is accessible through a searchable online database and downloadable data files. In addition to housing the LEIE and LEIE Downloadable Data File, OIG's Exclusions Page contains Quick Tips on how to use the LEIE, Frequently Asked Questions regarding OIG's Exclusions Program, information regarding how to apply for reinstatement, video podcasts, and contact information for the OIG Exclusions Program.

The online database contains the following information: (1) the name of the excluded person at the time of the exclusion, (2) the person's provider type, (3) the authority under which the person was excluded, (4) the State where the excluded individual resided at the time of exclusion or the State where

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<sup>23</sup> Information on the SDP can be found at <http://oig.hhs.gov/compliance/self-disclosure-info/index.asp>.

the entity was doing business, and (5) a mechanism to verify search results via Social Security Number (SSN) or Employer Identification Number (EIN). OIG plans to update the LEIE soon to include a National Provider Identifier, or NPI, for individuals and entities excluded after 2009 that have such an identifier and to include information regarding waivers of exclusion granted by OIG.<sup>24</sup> This will allow for an additional verification mechanism separate from SSN or EIN verification.

The LEIE Downloadable Data File enables users to download the entire LEIE. Supplemental exclusion and reinstatement files are posted monthly to OIG's Web site, and these updates can be merged with a previously downloaded data file. The Downloadable Data File does not contain SSNs or EINs. Therefore, verification of specific individuals or entities through the use of the SSN or EIN must be done via the Online Searchable Database. When checking the LEIE, providers should maintain documentation of the initial name search performed (such as a printed screen-shot showing the results of the name search) and any additional searches conducted, in order to verify results of potential name matches.<sup>25</sup> Some providers may choose to contract with another entity to perform their screening against the LEIE. These providers should be aware that because it is the provider's responsibility to determine whether employees are excluded, the providers will retain the potential CMP liability if they employ or contract with an excluded person.

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<sup>24</sup> A list of individuals and entities that have been granted an exclusion waiver by OIG is currently available on the OIG's website at [oig.hhs.gov/exclusions/waivers.asp](http://oig.hhs.gov/exclusions/waivers.asp) .

<sup>25</sup> Because the LEIE includes only the name known to OIG at the time of the individual's exclusion, all names used by the individual (e.g., maiden names) should be searched. OIG has provided a number of additional tips related to searching the LEIE at [oig.hhs.gov/exclusions/tips.asp](http://oig.hhs.gov/exclusions/tips.asp).

- *Frequency of Screening*

To avoid potential CMP liability, providers should check the LEIE prior to employing or contracting with persons and periodically check the LEIE to determine the exclusion status of current employees and contractors. Providers are not required by statute or regulation to check the LEIE. The LEIE is a tool that OIG has made available to providers to enable them to identify potential and current employees or contractors that are excluded by OIG. Because there is no statutory or regulatory requirement to check the LEIE, providers may decide how frequently to check the LEIE. OIG updates the LEIE monthly, so screening employees and contractors each month best minimizes potential overpayment and CMP liability. Additionally, in January 2009, CMS issued a State Medicaid Director Letter (SMDL) recommending that States require providers to screen all employees and contractors monthly.<sup>26</sup> In 2011, CMS issued final regulations mandating States to screen all enrolled providers monthly.<sup>27</sup>

- *Determining Which Individuals and Entities To Screen*

OIG recommends that to determine which persons should be screened against the LEIE, the provider review each job category or contractual relationship to determine whether the item or service being provided is directly or indirectly, in whole or in part, payable by a Federal health care

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<sup>26</sup> SMDL #09-001.

<sup>27</sup> See 42 CFR § 455.436. In response to comments, CMS clarified that this regulation does not mandate States to require their Medicaid providers to screen the providers' employees and contractors against the LEIE each month. However, CMS recommends that States consider making this a requirement for all providers and contractors, including managed care entities. See 76 Fed. Reg. 5862, 5897 (February 2, 2011).



program. If the answer is yes, then the best mechanism for limiting CMP liability is to screen all persons that perform under that contract or that are in that job category.

Providers should determine whether or not to screen contractors, subcontractors, and the employees of contractors using the same analysis that they would for their own employees. The risk of potential CMP liability is greatest for those persons that provide items or services integral to the provision of patient care because it is more likely that such items or services are payable by the Federal health care programs. For example, OIG recommends that providers screen nurses provided by staffing agencies, physician groups that contract with hospitals to provide emergency room coverage, and billing or coding contractors. Alternatively, the provider could choose to rely on screening conducted by the contractor (e.g., staffing agency, physician group, or third-party billing or coding company), but OIG recommends that the provider validate that the contractor is conducting such screening on behalf of the provider (e.g., by requesting and maintaining screening documentation from the contractor). Regardless of whether and by whom screening is performed and the status of the person (e.g., employee, subcontractor, employee of contractor, or volunteer), the provider is subject to overpayment liability for any items or services furnished by any excluded person for which the provider received Federal health care program reimbursement and may be subject to CMP liability if the provider does not ensure that an appropriate exclusion screening was performed.

- *Other Government Exclusion and Debarment Lists*

We have received questions regarding the differences between the LEIE and GSA's EPLS, which was recently merged into SAM. SAM includes OIG's exclusions but also includes debarment actions taken by Federal agencies. The LEIE lists only exclusion actions taken by OIG. We recommend that providers use the LEIE as the primary source of information about OIG exclusions because the LEIE is maintained by OIG; is updated monthly; and provides more details about persons excluded by OIG than GSA's SAM, such as the statutory basis for the exclusion action, the person's occupation at the time of exclusion, the person's date of birth, and address information. Also, because the LEIE is maintained directly by OIG, OIG's exclusions staff can respond to questions and verify information regarding persons identified on the LEIE. The effect of OIG exclusion is to preclude payment by Federal health care programs for items or services furnished, ordered, or prescribed by the excluded party. OIG exclusion does not affect a person's ability to participate in other Government procurement or non-procurement transactions. Moreover, OIG has no authority to impose CMPs on the basis of employment of (or contracting with) a debarred person. Additional information regarding SAM and debarment is available at <https://www.sam.gov>.

- *The National Practitioner Data Bank and the Healthcare Integrity and Protection Databank*

We have received questions regarding whether other sanction databases, specifically the NPDB and the Health Care Integrity and Protection Databank (HIPDB), can or should be used in addition to or instead of the LEIE as a means to identify sanctions imposed against providers. The NPDB was

established under the Health Care Quality Improvement Act of 1986. The NPDB is an information clearinghouse that originally collected medical malpractice payments paid on behalf of physicians, adverse actions taken by licensing agencies against health care practitioners and health care entities, adverse privileging actions, and any negative actions or findings taken against health care practitioners or entities by Quality Improvement Organizations and Private Accreditation Organizations. HIPDB was created by HIPAA to provide information on adverse licensing and certification actions, criminal convictions (health care related), civil judgments, exclusions from Federal or State health care programs, and other adjudicated actions or decisions.

Section 6403 of the ACA required the Secretary of Health and Human Services to eliminate duplicative data reporting and access requirements between the NPDB and HIPDB.<sup>28</sup> On April 5, 2013, the Secretary issued regulations to implement the changes required by section 6403 of the ACA to merge the two databanks. The NPDB will continue to collect and disclose both the traditional NPDB information (medical malpractice payments, adverse licensing actions, adverse privileging actions, and any negative actions or findings taken by peer review organizations) and the information previously collected and disclosed through the HIPDB.<sup>29</sup>

Although providers may choose to check the NPDB to obtain information about other types of sanctions reported in that database, the OIG recommends that providers use the LEIE as the primary database for purposes of exclusion screening for current and potential employees and contractors.

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<sup>28</sup> See section 6403 of the Patient Protection and Affordable Care Act, P.L. 111-148.

<sup>29</sup> See 78 Fed. Reg. 20473 (April 5, 2013); 42 C.F.R. 60.

For more information on the databanks, go to <http://www.npdb-hipdb.hrsa.gov/>.

## **CONCLUSION**

Since the publication of the 1999 Bulletin, the health care industry has significantly increased its efforts to comply with the rules governing the scope and effect of exclusion. This updated Bulletin:

- iterates earlier guidance on the scope and effect of an OIG exclusion,
- provides additional guidance on the scope of the payment prohibition and potential CMP liability,
- provides guidance on best practices for screening against the LEIE to ensure that providers do not employ or contract with an excluded individual, and
- directs providers to use OIG's SDP to self-disclose the employment of or contracting with an excluded person.

If you are an excluded person or are considering hiring or contracting with an excluded person and question whether or not an arrangement may violate the law, the OIG Advisory Opinion process is available to offer formal binding guidance on whether an employment or contractual arrangement may constitute grounds for the imposition of sanctions under OIG's exclusion and CMP authorities at sections 1128 and 1128A of the Act. The process and procedure for submitting an advisory opinion request may be found at 42 CFR 1008, or on the OIG Web site at <http://oig.hhs.gov/compliance/advisory-opinions>.