MEETING CHALLENGES OF EXPANDING SANCTION DATABASES

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Former HHS Inspector General

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October 21, 2014
1:00 PM EST
AGENDA

- Overview of Federal Exclusions and Debarments
- HHS OIG Screening Requirements and Guidance
- GSA Debarments
- Update on State Medicaid Databases
- Best Practices in Meeting the Challenge
INCREASED SANCTION SCREENING

- Sanction screening mandates continuing to expand
- OIG Bulletin updates their position
- GSA wraps EPLS into larger data system
- DEA and FDA expanding their sanction databases
- CMS calling for state mandated Medicaid screening
- Most States have Medicaid sanction databases
- Affordable Care Act mandates
MAJOR SANCTION DATABASES

- HHS OIG List of Excluded Individuals and Entities
- GSA System for Award Management exclusion list
- FDA Debarment List
- DEA Administrative Cases Against Doctors and Criminal Cases Against Doctors
- OFAC Specially Designated Nationals List (aka Terrorist Watch List)
- State Medicaid Databases (currently 36)
EXCLUSIONS & DEBARMENTS

• Program exclusion imposed by OIG
  - Excluded from federal HC programs for 5 years to indefinite
  - No payment for any items or services furnished, ordered or prescribed by an excluded individual or entity
  - OIG maintains the List of Excluded Individuals and Entities

• Debarment by GSA
  - Person/entity ineligible for federal contract/subcontracts
    Applies only to federal government agencies
  - For a set period of time and often follow suspension
  - GSA maintains the System for Award Management
• Risk of CMP liability
• Non-compliant with Conditions of Participation
• Possible submission of fraudulent claims
• Frequency of screening obligations increasing
• OIG enforcement efforts expanding
• Most involved a single excluded party
• Average around $300,000 per excluded party
• Number of cases growing every year
• Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (http://oig.hhs.gov/exclusions/advisories.asp)
  ○ First major update in 15 years

• Restates exclusion authorities

• Describes effect of exclusions

• Defines liabilities for engaging excluded party

• Clarifies issues raised about the LEIE

• Addressed differences between LEIE and SAM
  ○ OIG’s exclusions included in SAM

• LEIE should be considered the primary source
  ○ NPDB/HIPDB no substitute for LEIE screening
OIG SPECIAL ADVISORY BULLETIN

- Makes clear who should be screened
  - Parties who provide products/services directly or indirectly paid by a Federal health care program
- Evidence of those searched must be maintained
- Explains how to determine if someone is excluded
- Screen all names known (e.g. maiden name)
- Noted no statutory/regulatory frequency requirement
- LEIE updated monthly, so screening monthly “best minimize potential overpayment and CMP liability”
OIG Exclusion

- OIG will take action only when the party appears on the LEIE
- OIG exclusion does not affect participation in Government procurement or non-procurement transactions
- OIG has no authority on enforcing GSA debarments or other federal agency debarments
HOW TO DISCLOSE AN EXCLUDED PARTY

• OIG’s Provider Self-Disclosure Protocol to disclose and resolve the potential CMP liability

• Opportunity to avoid costs and disruptions associated with a government directed investigation and civil or administrative litigation

• Online self disclosure submission available
GSA debarment list is part of System for Award Management (SAM) that includes the Debarment List (EPLS), Central Contractor Registration, Federal Agency Registration, Online Representations and Certifications Application (ORCA)

Operational bugs, security breaches for users & data discrepancies in the beginning

Often incomplete debarment results
GSA SAM CONFUSION

- Many are confused about use of SAM data
- SAM is for use only by Federal procurement decisions
- GSA debarments are intended only for government agencies in making procurement decisions
- Rarely do health care providers meet these criteria
CMS ONLY ONE PUSHING GSA SCREENING

- Does not state frequency of screening
- Requires provider applicants screening against LEIE & SAM
- Mandates providers not to contract with anyone on SAM in order to maintain active enrollment
- Requires managed care plans to screen prior to hire or engagement and monthly
- Advocates to states to screen LEIE and SAM monthly
- No specific regulation that requires providers to screen SAM
CMS LACKS ENFORCEMENT TOOLS

- CMS lacks means to investigate/enforce GSA matches
- Can only call a violation of Conditions of Participation
- Grounds to sanction providers who are confirmed matches with SAM is questionable
- CMS never sanctioned anyone for failing to screen SAM
PROBLEMS WITH GSA SAM

- Debarment never intended for HC providers
- Not user friendly
  - Data lacks identifiable information for easy verification
  - No help provided to verify a potential “hit”
- Administrative debarments are advisory, can be waived
- No discretionary waiver guidance for HC entities
- Very few records are relevant to HC entities
- No specific CMS regulations requiring GSA screening
- Hits are common, legitimate ones very uncommon
- OIG adds LEIE data to SAM creating a redundancy
- OIG doesn’t call for screening against GSA
WAYS TO REDUCE GSA SCREENING BURDEN

- Screen only parties providing HC related services/items
- Screen at time of engagement and reduced frequency thereafter (e.g. annually)
- Conduct a “rolling screening” of program continuous screening of a small portion of the universe at a rate whereby to ensure all have been checked over the year
- Outsource the whole process to save time and costs, and gain confidence of accuracy of verification/resolution
CONTRACTORS MAY BE RELIED UPON TO SCREEN THEIR OWN EMPLOYEES

• Providers may rely upon contractors (e.g., staffing agency, physician group, or third-party billing or coding company) to screen
  ○ Provider must validate that screenings are being conducted by requesting and maintaining documentation.

• Regardless of who conducts screenings, provider is subject to overpayment and CMP liability if they do not ensure that appropriate exclusion screening was performed.
EXCLUSION APPLIES TO SERVICES/PRODUCTS NOT DIRECTLY BILLED

- No payment permitted for non-direct patient care items/services, such as:
  - Services separately billed or included in bundle payment
    - Preparing surgical trays
    - Reviewing treatment plans
    - Inputting prescription information for pharmacy billing
    - Filling prescriptions for drugs
    - Providing transportation services
  - Administrative and management services
    - Serving in executive or leadership role
    - Health IT services and support, strategic planning, billing and accounting, staff training, and HR, unless wholly unrelated to Federal HC programs
Screen LEIE before engagement, periodically thereafter

Employees, contractors and vendors or anyone included in claims submitted for payment

Includes physicians who are granted staff privileges

Best to include volunteers, unpaid others

Many states mandate Medicaid sanction screening

If State requires monthly screening, advisable for LEIE

NOT THOSE YOU HAVE NO CONTRACTURAL RELATIONSHIP
Effective January 2011, under Section 6501 PPACA

State Medicaid agencies to exclude individuals & entities when terminated from Medicare or Medicaid
• Should check monthly for exclusions
• Should advise providers upon enrollment and re-enrollment of their obligation to screen all employees and contractors against the OIG LEIE
• Should screen against GSA
• Should require providers agreement to comply with obligation to screen as a condition of enrollment
• Medicaid payments are prohibited for all items/services furnished by excluded persons and entities
STATE TRENDS

- States establishing sanction screening sites/databases
- Require providers to screen Medicaid exclusions
- State enforcement initiatives
- 36 Medicaid exclusion lists with more coming
### STATE MEDICAID PROGRAMS

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<thead>
<tr>
<th>Alabama*</th>
<th>Illinois</th>
<th>Minnesota</th>
<th>Ohio</th>
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<td>Mississippi</td>
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<td>Louisiana**</td>
<td>New Jersey***</td>
<td>Texas *</td>
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<td>Nevada</td>
<td>Washington</td>
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<td>Massachusetts*</td>
<td>North Carolina</td>
<td>West Virginia****</td>
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<tr>
<td>Idaho*</td>
<td>Michigan</td>
<td>North Dakota</td>
<td>Wyoming*</td>
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* Agency requires monthly screening of the Medicaid list
** Agency requires monthly screening against Medicaid, OIG LEIE and GSA SAM
*** Required to screen OIG LEIE, Treasurer’s Exclusion List, NJ Division of Consumer Affairs Licensure Database, NJ Department of Health and Senior Services Licensure Database and CAN and Personal Care Assistant Registry (if applicable) on a monthly basis.
**** Required screening OIG LEIE and Sanctioned/Excluded Provider Listing on an annual basis
EFFECT OF SCREENING EXPANSION

- Complexity of meeting obligations increasing
- Cost of screening rising
- Staff time devoted to screening is expensive
- Difficulties in resolving “raw hits”
- Added burdens to create reports evidencing the work
- Frequency of screening becomes a difficult decision
- Must coordinate HR, Compliance, procurement, etc.
8 FACTS WORTH PONDERING

1. OIG will take action enforcement action regarding LEIE
2. OIG won’t take action on “hits” with other databases
   - GSA, FDA, DEA, and other Federal sanction lists
   - Medicaid exclusion databases
3. GSA SAM applies only to federal government agencies
4. GSA never taken action outside of government agencies
5. CMS calls for GSA screening, but no there are no penalties
6. CMS has never taken action on sanction “hits” agencies
7. CMS has no enforcement process to take action on “hits”
8. Terminating contracts based on GSA “hit” is legally questionable
ESTABLISH A PROCESS

- Who should check?
- Who should be screened?
- When and How Often?
- Which Databases?
- What Methods?
• Document sanction screening results
• Get certified reports from vendors
• Keep records of screening results
• Store records with Compliance for ongoing screening
• HR store screening records for time of hire
CERTIFIED REPORT OF RESULTS

SANCTIONS SCREENING AND VERIFICATION SERVICES REPORT

Report Date: [DATE]

Batch File name: [CLIENT NAME]

I. Executive Summary

The Compliance Resource Center utilizes Sanction Screening Services to identify sanctioned, excluded and/or high-risk individuals from federal and state health care agencies. In accordance with federal and state regulations, the Compliance Resource Center provides screening against the Department of Health and Human Services, Office of Inspector General's List of Excluded Individuals and Entities and the General Services Administration’s System for Award Management Exclusion List.

Also, in accordance with the Department of Health and Human Services, Office of Inspector General's State Medicaid screening guidelines, [STATE] provides a list of excluded entities to aid in the identification of excluded individuals and entities.

The findings of the sanction screening and verifications services are included in the Compliance Resource Center’s Detailed Results Report.

II. Background and Methodology

The Compliance Resource Center (CRC) conducted sanction screening services on behalf of [CLIENT NAME] on [DATE]. CRC staff utilized the Sanction Screening Services (S3) tool to conduct sanction screenings against the following agencies:

- Department of Health and Human Services, Office of Inspector General’s List of Excluded Individuals and Entities
- General Services Administration’s System for Award Management Exclusion List
- [STATE] Medicaid List

[CLIENT NAME] provided CRC with a list of individuals and entities in MS Excel format. The original file(s) submitted were: [FILE NAME]. The file(s) were formatted to fit the S3 template files compatible with the tool and necessary to run the files. The template files were uploaded and imported into S3 and a

APPENDIX A - Investigations of Potential Hits

A. Investigations of Individuals

We investigated [NUMBER] individuals who were found as potential hits. Based on our investigation, one individual was a confirmed match to the OIG LEIE and the GSA SAM exclusion lists. Of the [NUMBER] individuals submitted for screening [NUMBER] were identified as “Not Found.” More information is available in the attached Detailed Results Report.

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<th>Verification Result</th>
<th>Last Name</th>
<th>First Name</th>
<th>Middle Name</th>
<th>NPI</th>
<th>Sanction Date</th>
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<td>Gabriel</td>
<td>Tony</td>
<td>D</td>
<td>1009797281</td>
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MUST MAINTAIN DETAILED RECORDS OF ALL NAMES SEARCHED

Total Records: 13
Search conducted 6/10/2010 7:30:43 AM on LEIE
Source data updated on 6/10/2010 12:00:00 AM.

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<td>2</td>
<td>COLEMAN</td>
<td>CHRIS</td>
<td></td>
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<td>3</td>
<td>GABRIEL</td>
<td>TONY</td>
<td></td>
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<tr>
<td>4</td>
<td>GAGE</td>
<td>MITCHELL</td>
<td>01/06/35</td>
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<td>5</td>
<td>GAGNON</td>
<td>DIANN</td>
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<tr>
<td>6</td>
<td>HAGIWARA</td>
<td>EDELTRAUD</td>
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<td>REBECCA</td>
<td>05/09/70</td>
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<tr>
<td>9</td>
<td>HAH</td>
<td>MING</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>HAILE SELASSIE</td>
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<tr>
<td>11</td>
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<td>12</td>
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<td>13</td>
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<td>JASPER</td>
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<td>GABRIEL</td>
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<td>D</td>
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<td>HAGLER</td>
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<td>D</td>
<td>COUNSELING CENTER</td>
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<td>P O BOX 1032, #348003-013</td>
<td>COLEMAN</td>
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<td>33521</td>
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<td>MING</td>
<td>KOW</td>
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<td>E</td>
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<td>BUSINESS MANAGER</td>
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<td>RR 2</td>
<td>BRIDGEVILLE</td>
<td>DE</td>
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<td>04/30/1997</td>
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RESOLUTION OF “HITS”

• Initial match by first and last names
• Verify match using:
  o Date of birth
  o Social Security Number
  o Middle name / initial
  o Maiden name
  o Address (at time of exclusion)
  o Occupation (at time of exclusion)
• Use LEIE as primary source to follow up on SAM “hits”
• Confirm with OIG, State Medicaid Agency
• Confirm with individual
SEARCH TIPS

- LEIE: Information about party at time of exclusion
- Former names (e.g., maiden, previous married name) should be searched at time of hire / engagement
- Check hyphenated name under each of the last names
- Double-check spelling of names
- Final step of identity verification using SSN or EIN
IN-HOUSE vs. OUTSOURCING

- Consider your resources:
  - Staff
  - Time
  - Cost

- Also consider:
  - Number of individuals to screen
  - Frequency of screening
  - Documentation / evidence
  - Number of sanction databases to screen
### COMPARISONS

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<thead>
<tr>
<th>In-House</th>
<th>Outsource</th>
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<tr>
<td><strong>Advantages</strong></td>
<td><strong>Advantages</strong></td>
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<tr>
<td>o Use employees</td>
<td>o Maintains/updates data</td>
</tr>
<tr>
<td>o Can be done anytime</td>
<td>o Far less expensive</td>
</tr>
<tr>
<td>o Results are kept internal</td>
<td>o Use only a fixed fee vendor</td>
</tr>
<tr>
<td><strong>Disadvantages</strong></td>
<td><strong>Disadvantages</strong></td>
</tr>
<tr>
<td>o Costly to build/maintain</td>
<td>o Costly if charged on volume</td>
</tr>
<tr>
<td>o Updating time consuming</td>
<td>o Trained staff verify hits</td>
</tr>
<tr>
<td>o Difficult to resolve “hit”</td>
<td>o Monthly certified report</td>
</tr>
<tr>
<td>o Hard to keep up with changes</td>
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</tr>
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Sanctions batch Search for excluded individuals or business entities

Step 1 (Upload):
Select file: [Choose File] No file chosen

Templates:
Please right click on this hyperlink and select save target as to download the Names template file.
Please right click on this hyperlink and select save target as to download the Business template file.

Step 2 (Import):
Search criteria:
- Name
- Business

Step 3 (Search):
Select Federal database(s)
- (OIG) List of Excluded Individuals/Entities
- (SAM) General Services Administration System for Award Management
- (OFAC) Specially Designated Nationals List
- (NPI) NPI Registry
- (UPIN) Unique Provider Identification Number
- (DEA) DEA Active Controlled Substances Act Registrants Database
- (FDA) FDA Debarment List
- (CCAD) DEA Criminal Cases Against Doctors
- (ACAD) DEA Administrative Cases Against Doctors
- (OIGW) Waivers of OIG/HHS exclusions

Select State database(s)
Disclaimer
- Select State Databases
8 TIPS IN SELECTING A VENDOR

1. Determine their screening tools and databases
2. Ask for fixed fee, not per name search fee
3. Ensure contract permits termination at anytime
4. Make sure you have references from the vendor
5. Use vendors with only many years of experience
6. Ask about other benefits (policy templates, help desk, etc)
7. Vendors are available to outsource the entire process
8. If vendor screens for you, ensure certified reports
QUESTIONS

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Subscribe to Kusserow’s Corner - Compliance Blog
http://health.wolterskluwerlb.com/kusserow_corner/
REFERENCES

  http://oig.hhs.gov/exclusions/effects_of_exclusion.asp