SANCTIONS SCREENING PLAYBOOK

Healthcare Edition

ETHICO

Ethico is on a mission to make the world a better workplace by giving leaders who care actionable insight tools, and services to mitigate risks, engage employees, and build strong cultures. We thought we'd talk to some of our customers and screening experts about what it takes to build not just a good screening system, but a great one.

We've captured their thoughts and insights in this Playbook, along with a few we've learned along the way. Our goal is that this Sanction Screening Playbook serves as a reference for compliance leaders to improve their screening practices and perhaps offer some unexpected pieces of wisdom.

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"During the review process, the focus for Ethico's SanctionCheck system is to prevent False Negatives) since these represent the greatest danger to our clients," said Co CEO and Chief Servant Nick Gallo. "If not caught, sanctioned individuals will slither into your organizations, building up fines and potentially corrupting your culture - especially if this sanctioned party has access to subordinates who come to see his or her non-compliance as appropriate."

WHY IS SANCTION SCREENING IMPORTANT?

Begin by understanding what sanction and exclusion screening is: a process healthcare businesses must undertake to determine whether an employee or business partner is barred (that is, sanctioned or excluded) from participating in federal healthcare programs such as Medicare and Medicaid. If the employee or business partner is excluded, the healthcare business cannot work with that person, under threat of monetary penalties or even being excluded itself.

KEEP IN MIND

For compliance with the **Office of the Inspector General (OIG):**
Employees, vendors, & contractors must be screened against the LEIE

For compliance with the **Centers for Medicare & Medicaid Services (CMS):**
Sanction screening is a condition of payment

Since the objective is to avoid working with excluded parties, the key to successful compliance is screening. And screening means checking names against databases of sanctioned parties for possible matches, over and over. At an abstract level, that object is easy to understand. The challenge is to implement efficient, effective procedures to achieve it.

So why is sanction screening important? It's a compliance requirement, it reduces regulatory enforcement risk, protects your patients from harm, protects your business from litigation, and supports an ethical workforce.

ROUND ONE

You will need to get your list of names, ideally with specifics like ID numbers and full names. This stage will be fast for those with automated screening systems which check names against multiple databases at once.

ROUND TWO

Unless you have a powerful sanction screening tool, you will likely see a few potential matches come back after Round One. You will need to get new information (if you did not have it during Round One) to screen again such as a date of birth, NPI, etc.

VERIFICATION

There are varied approaches to verifying if a name is a match after round two. Some will not think it is worth the effort. Others will have the potential matches sign affidavits attesting they are not a listed excluded party.

POST-SCREENING

This stage occurs after all screening and verifications have been completed. Ideally, most post-screening will consist of giving HR or procurement the all-clear on a new hire or vendor. But when a confirmed match has been found this stage will involve assessments and disclosures. Go read **Page 10** to learn more.

1. Names compiled
2. One name or a batch are screened against lists
3. Ruled out names cleared
4. More info requested to rule out any potential matches
5. Potential matches screened with new info
6. Ruled out names cleared
7. Have potential matches sign affidavits to rule out names
8. Matches confirmed if affidavits left unsigned
9. Confirmed matches dealt with according to policy
10. Assessment of possible liability for non-compliance
11. Self-disclose non-compliance to regulatory agency
12. Reporting/Auditing

THE SCREENING PROCESS

If a healthcare organization wants to do business with the U.S. government, they must perform screening. This is a simple fact of life for them. What appears here is a general outline of the screening process gleaned from insights provided by Ethico's customers and our own screening experts. Keep in mind this represented a general screening process and while most organizations will follow this pattern, but there can be variations.

MANY ENDPOINTS BUT NO END

The screening process does not need to follow all of these steps in the exact order shown. You may find no matches on the first round of screening or the information acquired in the second round eliminated all your potential matches. There are many endpoints to the one screening you are conducting. But the cycle of screening will never end when regulators are constantly updating there lists (eg. the LEIE is updated monthly). A proper screening program will screen all employees and vendors on a monthly, quarterly, or biannual basis to ensure no one has been placed on a list from the time of their last screening.

FALSE POSITIVES ARE A HASSLE
FALSE NEGATIVES ARE A DANGER

You will hear a lot about tools claiming they minimize or eliminate *False Positives* (or false matches), which is a good line since clearing out false positives is one of the biggest hurdles in sanction screening. But what you are not told is how a narrowed focus on reducing false positives increases your risk of what is known as a **False Negative**.

If you have ever heard talk about false negatives and false positives, then you are dealing with the **hypothesis testing**. And if we're dealing with sanction screening, you're going to be using the **null hypothesis**.

The null hypothesis is the basis of most sanction screening systems as it asserts that THING 1 is not related to THING 2. The null hypothesis is assumed true unless evidence shows otherwise. In the context of sanction screening your hypothesis is:

Screened Name ≠ Any Sanctioned Party

This means when you screen a name against a list you are basically conducting tests to prove your hypothesis. When you screen a newly hired physician or nurse practitioner your hypothesis is that they are not sanctioned by regulators.

Results of Screening

	Not Sanctioned	Sanctioned
Not Sanctioned (Positive)	**True Positive** Good Employee found Unsanctioned	**False Positive** Good Employee found Sanctioned **<ERROR>**
Sanctioned (Negative)	**False Negative** Bad Employee found Unsanctioned **<ERROR>**	**True Negative** Bad Employee found Sanctioned

Actual Truth

In statistics and data analysis it's common to talk about these two types of errors:

1. False Positives (Type 1 Errors)
This is when you think a searched name has been matched based on a screening, but the screening is incorrect because the person is not the same at the one sanctioned. A lot of manual screening consists of clearing the false positives out and this practice can become a tedious routine, which in turn increases the chance of a human error.

2. False Negatives (Type 2 Error)
This is when you rule out name or entity because your screening results claim they are not on a database's list, but for one reason or another your results are incorrect. A false negative poses a much greater risk to patients and must be prioritized as a point of excellence in your exclusion screening process.

JUST F.Y.I.

If you're curious about what *True Positive* and *True Negative* results are, it's pretty simple. A True Positive result is one where the searched name or entity is correctly identified as being unsanctioned. True Negative is when the searched name or entity is correctly identified as being sanctioned.

The use of the word "true" for these simply refers to the screening results being correct. And the use of the term "false" is used to describe the errors.

FINDING OUT WHICH DATABASES WORK FOR YOU

Working with the right data is crucial. So is putting together the right mix of technology, internal procedures, and outside expertise to assure that your screening program has maximum efficiency: able to identify the greatest number of possible matches at the lowest cost to your budget. Compliance officers should think through those strategic questions at the beginning, so they don't squander resources later.

One hurdle is simply to gather the most appropriate data so your screening can unfold as efficiently as possible. For example, companies can use the Social Security Death Master File to find people using the Social Security numbers of someone deceased — a nifty way to identify any potential fraudsters, regardless of whether they are on List of Excluded Individuals/Entities (LEIE) or System Award Management (SAM) List. Numerous other databases of excluded parties exist, either for a price or freely available for download.

Think About the Best Sources of Information for Your Screening Program

You need to consider which databases provide the best chance of finding a sanctioned party at the lowest cost to you and your team. A free database may be unreliable, or require so much integration into existing procedures that it breaks your budget. Paid databases might be too expensive for your needs. Review all the databases that could help with screening compliance; consider how you might use them given existing constraints with your budget, staff, and technology. Use the ones that will deliver the most ROI.

Which States' Medicaid Databases Should You Use?

Ethico's screening experts know it is unlikely you will want to screen all Medicaid databases unless your organization is located in every state. Budgetary and time limitations play a role in this decision. Therefore, they typically recommend screening the states where a client has a location based, and possibly any neighboring states. How many of these lists a client wants to screen is determined by how much risk a program is willing to take on. It should be noted if you do business in certain states they will require their list to be screened such as New York and New Jersey.

THE BIG FOUR DATABASES

The most basic databases needed for effective sanctions and exclusion screening

- OIG - List of Excluded Individuals & Entities (LEIE)
- GSA - System of Award Management (SAM) List
- SSA - Social Security Death Master File
- State Medicaid Exclusion Lists

YOUR GOOD PRACTICE DATABASES

The use of these databases is a good practice for screening programs seeking to offer more robust protections.

- CMS - Preclusion List
- DEA - Administrative Actions Against Registrants
- DEA - Criminal Cases Against Doctors
- NPPES - National Provider Identifier
- OFAC - Specially Designated Nationals (SDN) List

YOUR NEED-TO-KNOW DATABASES

These are examples of databases for specific risks or healthcare industry segments like veterans' health, research, pharmaceuticals, med schools, etc.

- CMS - Open Payments List of Teaching Hospitals
- CMS - Opt-Out Affidavits
- FDA - Disqualified and Restricted Lists
- FDA - Debarment List
- ORI - PHS Administrative Action Report List
- US Military Health System Sanctions List

DEALING WITH YOUR POTENTIAL MATCHES

Moving Your Process Forward - Rule Them Out or Confirm Your Match?

Screening is a complex process that checks many pieces of data against other pieces of data. After the first round of screening, it is inevitable that you will receive several matches back. These we call **Potential Matches** because we need to ensure we have the correct evidence before we flag them. With the types of databases you will be dealing with, errors are inevitable in the screening process. **False negatives**, where you fail to detect a person who is sanctioned — can bring much more serious consequences to the company than **false positives** (flagging someone as excluded when they aren't). Reducing the risk of dangerous false negatives must be a high priority when you are dealing with your first round of potential matches.

Types of Exclusions

There are a variety of reasons why a healthcare professional might appear on the LEIE. In fact, there are two types of exclusions: mandatory exclusions, which bar the individual from all federal healthcare programs; and permissive exclusions, which are at the discretion of the OIG and tend to bar the individual for a shorter period of time. It's important to review the potential matches to make sure they are not someone with an active exclusion. On other lists some providers with temporary sanctions can still appear after they have been reinstated.

1. **Mandatory exclusions include:**
- Medicare or Medicaid fraud
- Felony convictions for fraud, theft, or financial misconduct
- Felony conviction for distributing or prescribing controlled substances

2. **Permissive exclusions include:**
- Misdemeanor convictions for health care fraud
- Suspension, revocation, or surrender of a medical license due to professional incompetence
- Engaging in unlawful kickbacks

With so much data, errors like false positives and false negatives are inevitable. It's handling these errors which allows a skilled screener to rule out names from Potential Matches.

IN THE LEIE DATABASE:

- 1.375 million data points
- Over 75,000 entries
- 18 possible data fields per entry

IN THE SAM DATABASE:

- 4.18 million data points
- Over 144,400 entries
- 29 possible data fields per entry

SOME RULE OUT RULES FROM COMPLIANCELINE

What follows are a few examples of the type of rules used by Ethico's screening platform. These rules help to whittle down the number of false positives that come back as Potential Matches and ensure a more accurate and streamlined process.

100% Rule
If 100% of the name being searched is contained in the sanctioned name, or vice versa, the name should be marked as a potential match (subject to the Male Last Name Rule below).

Henry, Robert - Henry, Robert Michael - Potential Match

Nickname Rule
Nicknames can determine if a name is a possible match. For example, Will is a common nickname for William, so to avoid a False Negative, we would flag that as a potential match.

Smith, William J. - Smith, Will J. - Potential Match

Middle Name Rule
Middle names provide much information value in the review process. Because it is not uncommon for individuals to go by their middle names, we need to consider First and Middle Names as potentially interchangeable.

Jones, Christopher Robert - Jones, Robert - Potential Match

Male Last Name Rule
This rule assumes that men will retain their last name throughout their lives; thus, if the matching last name is in different positions relative to the comma in the searched and sanctioned name, it can be ruled out.

Simmons, Daniel - Brown, Daniel Simmons - No Match

Double Last Name Rule
There is a wide variety of ways that individuals handle last names, influenced by family tradition, culture, etc. For example, a child may be given both their parents' last names at birth, but may only go by their father's name in official capacities. Thus, if a searched name has a double or hyphenated last name, and one of those names is in the Last Name position of the sanctioned name, we should flag it as a potential match to avoid a False Negative.

Smith Calhoun, James - Smith, James - Potential Match
- Calhoun , James - Potential Match

Maiden Name Rule
The Maiden Name rule addresses the tradition of women taking their husband's surname after marriage, while retaining their Maiden Name as their Middle Name. Thus, female names with the last name in the middle name position should be flagged as possible matches.

Henderson, Carlie Jones - Jones, Carlie - Potential Match

There are many other rules that can be incorporated to enhance your screening process such as the Transposed Name Rule, the Gender Rule, the Hispanic Name rule. And don't forget rules to incorporate identifiers such as date of birth and national provider ID (NPI) which can provide certainty on potential name matches.

SEVEN BEST PRACTICE OF SANCTION & EXCLUSION SCREENING

1. **Get the Right Info Up Front:**
   Make certain the right internal procedures are set up so that when healthcare provider is being considered for employment, you receive all the crucial screening information at once. This means you find out full names, maiden names, DOB, NPI numbers, Social Security numbers, etc. If you are not getting all this information up front you run the risk of delays as you go back and forth with HR, procurement, recruiters, etc. to get the details you need **to make the best determinations on potential matches.**

2. **Automate the Routine and Mundane**
   Your team's time is wasted with unnecessary work, excessive search review tasks, hand-offs across the team, and shuffling or tracking the steps in the process. Not to mention the chance of human error increases when activities become too routine. If your team's eyes are glazed over, they're going to miss details. Find the right tools to automate the screening process, but be careful with this. **You must automate wisely.** An overly mechanized process ignores the discretion that makes compliance leaders necessary.

3. **The Goldilocks Dilemma: Using the Right Number of Databases**
   "This Screening Program has too many lists, this one has too few, and this one is just right."
   Finding the right number of databases to screen against depends on several factors including your organization's locations, risk tolerance, and your segment in the healthcare industry. Too few lists mean higher risks. But on the other hand, if you indiscriminately search every list available, you're at risk of spending too much effort on the wrong focus, burning out your team, and wasting your budget. **Take an intelligent, balanced, and contextualized look at which lists are going to hit that sweet spot** of having a high potential (not just some vague remote chance) of identifying a sanctioned party that is putting your company at risk.

4. **Not over-relying on public databases**
   A proper sanction screening process should acquire and consider information available on lists which are not provided publicly in posted databases for download from their agencies. **Sanctioning agencies have powerful, non-public data which offers insight and clarity at a crucial stage in the process** you can access only by interacting with them. For example, the OIG's LEIE and GSA's SAM list are publicly available for download; however, for the CMS Preclusion List you must subscribe to CMS's portal. Using these non-public databases further helps to rule out an exclusion and avoid having an unnecessarily uncomfortable conversation with an employee or potential employee. Additionally, it can give you a much needed confirmation before engaging in a lengthy investigation so you can act quickly and with assurance to remove a disqualified physician.

5. **Build a system to catch False Negatives** (see page 4)**, not just reduce false positives**
   You will encounter false negatives when your screening results fail to reveal that a person or entity is actually sanctioned. Using exact match rules for screening will reduce your false positives, but false negatives can slip through. You must use better rules (see page 8) in place of an exact match rule to form the foundation of a proper screening system.

6. **Use the Social Security Death Master File**
   If you're not checking against the Social Security Death Master File, you may have a physician or an employee who has submitted a fraudulent Social Security number caring for your patients. Fraudulent Social Security numbers expose your organization and patients to risk. Leverage the Social Security Death Master File correctly before searching sanction lists to make sure that your employees have submitted a proper number.

7. **Handle Your Employee Interactions Appropriately**
   When the matching data is concerning enough that you need an additional check even though you don't know for sure, you will want to engage the employee or physician in a discussion where you share your discovery of the sanction with them. If you terminate an employee anytime you see something questionable, or worse, never have a discussion with the potential match, you're probably making mistakes.

ENHANCED PROCESSES OF SANCTIONCHECK

It would be impossible for us to produce this playbook without mentioning our screening product, SanctionCheck, at least once. Here we show you a comparison of the screening process differences between using a screening platform (specifically with SanctionCheck) and manual screening without any sort of platform. There is an obvious higher demand of time and focus in the manual process with a lot of effort spent moving between lists, formating the data, and eliminating false positives.

MANUAL

1 Names compiled

2 Go to a database directly to screen a name or batch

3 Screen a name or batch with each database one at a time

4 Verify the data fields for each potential match in database

5 Sort out false positive matches from any results

6 More information acquired for any incomplete data

7 Names cleared once ruled out in all databases

8 Sort out any new false positive matches

SANCTIONCHECK

1 Client supplies compiled names in templates

2 Compiled names uploaded to SanctionCheck platform

3 Names screened against all databases at once

4 Ruled out names cleared

5 Matches are designated as "Pending Review"

6 SC Account Manager reviews Pending Review results

7 Exclusion Results Certificate produced for client

8 If any remaining potential matches, more info requested

9 Account Manager uses non-public agency data to rescreen potential matches

10 Remaining potential matches are sent an attestation letter

11 Signed letter returned by deadline, name ruled out

12 If letter unreturned, potential match is treated as confirmed

THE 3 LEVELS OF SERVICE

ComplianceLine offers three levels of SanctionCheck service.

The level of SanctionCheck service reflected here is what is known as Full Service, meaning SanctionCheck's account managers will see your screening process through from start to stop and all you do is provide the initial list, any additional info, and approval on the use of attestations.

The next tier of service is the partial option wherein you provide your batch of names and we screen as much as possible with you finishing off the final verifications.

The third and final option is the self-service choice. You would be able to access the screening platform yourself and run your own checks.

SO I'VE GOT A CONFIRMED MATCH. NOW WHAT?

The occasion of finding a true confirmed match is uncommon enough that many screeners will find themselves thrown off when they actually encounter one. But it happens and it is what this whole screening process has been about.

When a match arises, the compliance team must be able to take several more steps:

1. Investigate and confirm whether the employee is indeed an excluded party. Determine if the exclusion is active or if it has expired.

2. Determine appropriate next steps based on your organization's policies. This could mean termination.

3. Investigate potential misconduct such as fraud, kickbacks, or patient harm during the employees term.

4. Self-disclose any uncovered non-compliance. It might feel like a walk of shame, but the penalties will be exponentially worse if it is discovered you knew about this and did not disclose it. Some sanctioning agencies, such as the OIG, have online forms to submit self-disclosures.

5. If there was an incident, audit your screening process to find out what went wrong. Perhaps a sanctioned physician or nurse was allowed to start before your screening could be completed. Or it might be your screening rules are not set up to prevent false negatives.

And always remember: strong sanction screening capability is good for your business. It reduces regulatory enforcement risk and other threats of fraud, patient abuse, and litigation. Done right, sanction screening pays for itself, in the form of costly mistakes that never happen and an engaged, ethical workforce that can keep your business moving in the right direction.

Ethico's Values

Ethico empowers leaders who care, this is how we become the best company in our market. Our values and brand promise are what guide us along this path. Here is what that promise means to us and how we partner with our customers:

C: Client-First: means we put your needs first and focus on the long-term. Sometimes we will forego what is best for our bottom-line in the short-term for what is best for the partnership over the long term.
A: Accountability: means we are accountable for our actions and responsible for our impact. This means consistently delivering on our commitments and owning mistakes when they occur with transparent, candid communication.
R: Responsiveness: refers to both the micro and the macro: The micro is around being quick to respond to questions and to provide information or results to our partners, because you need actionable info to do your job and the longer it takes for clarity, the longer risks exist in your system. The macro refers to responding to the changing risk and regulatory landscape as your organization grows and both requirements and best practices change.
E: Excellence: Leading with quality solutions that are both sustainable and thoughtful. Doing the right things right.
S: Servanthood: Selfless elevation of the needs of others.

We're proud to support the voice of nearly 7,000,000 employees across the clients we serve with our services. We look forward to further collaboration and together making the world a better workplace.

Using the Right Resources for an Integrated Approach

Some screening tasks can be automated, such as comparing employee data against exclusion lists. Along similar lines, some tasks can be outsourced to firms that specialize in specific screening tasks. Find the right mix of technology, in-house personnel, and outside expertise to achieve the most efficient screening possible.

Use Program Resources Wisely, So You Can Take Action

The more automated and error-proof screening is, the less burdened your compliance team is with mundane tasks such as data search or list maintenance. Your team can instead focus on risk analysis, investigation, and remediation of other problems that screening brings to light. The result is better use of compliance resources and more effective compliance overall.

Procurement Integration

Screening suppliers and vendors is just as essential to compliance as screening individuals and many regulatory penalties come from weak screening of third parties. This sort of screening is much the same as screening individuals and it follows the same process. Like people, organizations can also be guilty of fraud, waste, and abuse of government sponsored healthcare programs. Ensure your procurement teams are well-informed of the screening process and know the risks of using excluded vendors. They should also be aware of the risks in doing business with organizations located in politically sanctioned nations or with ties to criminal organizations. Screening against OFAC's SDN List is just the tip of the iceberg in this regard. Make sure due diligence protocols are being adhered with in procurement as matters of compliance will not always be a top-of-mind concern for these departments.

Integrate Screening with the Rest of Compliance

Sanction screening is a crucial compliance duty, but it is still only one part of a larger compliance program. Compliance officers should ensure that screening doesn't happen in a vacuum, but rather, informs and supports other parts of the compliance program for maximum success. For example:

INVESTIGATIONS: When screening a Potential Match, a deeper investigation of the data should follow. For example, a match might be a false positive or have an expired exclusion. Determining the full facts of a screening issue is important, both to keep good employees on staff and to avoid patient harm or litigation risk. Investigation protocols must be able to "pick up" screening evidence and carry it further.

TRAINING Employees should receive training and other messages from senior leaders about screening: that it exists, and misconduct that puts an employee on a list could put their job and long-term career prospects in serious jeopardy. The mere existence of screening can dissuade employees from misconduct— so put that fact to work!

INTERNAL HOTLINE: Most employees want their businesses to succeed, and will raise concerns via internal compliance hotlines. So when a report arrives about a coworker or third party who seems suspicious, screening can be an early step to investigate those issues. Internal reporting and screening procedures should support each other to help compliance find the truth about allegations.

"While SanctionCheck has a focus on preventing false negatives. False positives create significant obstacles to efficiency and a proper exclusion screening program will naturally eliminate them," said Co-CEO Giovanni Gallo. "For example, if, an individual is still a 'Potential Match' at the end of the screening process, a proper exclusion screening program would provide the opportunity for that individual to sign an affidavit attesting to whether they are the sanctioned individual or not. This final step removes much of the trouble with false positives.

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