DESCARTES™

Healthcare Exclusions Screening

Six Steps for Enhanced Compliance

Introduction

International regulations ban certain individuals or organizations at home and abroad from working with U.S. businesses. The intention is to prevent fraudulent activities, abuses, or national security issues. More importantly, compliance helps facilitate organizational goals and enables growth.

When it comes to following these rules and regulations, it's important to understand that the healthcare industry is no exception. For example, the U.S. Office of the Inspector General (OIG) is one of the government agencies responsible for handling compliance exclusions screening rules for healthcare organizations and institutions. Others include the General Services Administration (GSA), Drug Enforcement Administration (DEA), Medicaid, and the Office of Foreign Assets Control (OFAC).

To mitigate the risk of costly monetary fines and reputational damage associated with non-compliance, health and pharmaceutical companies need to screen for sanctioned parties (also known as restricted, denied, debarred, blocked parties, among others) and stop themselves from working with these banned entities. It is important to note that sanctioned parties can be from either foreign regions or domestic areas, and organizations need to consider local screening as well.

While consistently screening for sanctioned parties at a high level is difficult, the importance of maintaining strong compliance cannot be understated. Discovering how you can help your organization in this manner is vital , whether you are a dedicated export control officer, a compliance leader, a research compliance and integrity manager, or even General Counsel.

The more partnerships you make with third-parties and the more you expand business operations into other regions, the more risk that needs to be managed through exclusions screening.

The goal of this guide is to provide healthcare organizations with actionable steps they can follow to achieve compliance within their field.

Businesses across industries must screen against exclusions lists. Organizations in the healthcare industry are no exception.

Step One: Know Your Lists

There are numerous regulations that dictate what entities healthcare organizations cannot interact with. Take the following lists of excluded individuals and entities into account when designing your export compliance program.

The Office of the Inspector General's List of Excluded Individuals and Entities

What is the OIG exclusion list? The Office of the Inspector General (OIG) maintains the List of Excluded Individuals/ Entities (LEIE) to ban certain parties from federally funded healthcare programs. OIG exclusions can be the result of any number of causes:

- Fraudulent activity related to Medicare, Medicaid, or any other state or federal healthcare programs;
- Convictions of producing or distributing controlled substances;
- Poor quality services offered in the past;
- A history of patient abuse or neglect; and
- Defaulting on health education loan obligations.

These reasons can lead to either mandatory exclusions or permissive ones, in which the OIG uses its own discretion on whether to add the entity to the list. Those who end up on the federal OIG exclusion list must not receive payments for services under federal healthcare programs, though they can still receive benefits.

The System For Awards Management of the General Services Administration

Ever since the implementation of the Affordable Care Act, the Government Services Administration (GSA) maintains an updated version of its healthcare compliance exclusion database known as the System For Awards Management (SAM), which was formerly known as the excluded parties list system (EPLS).

Individuals and entities on the EPLS or SAM cannot receive federal contracts. That is, federal program payments for products made by excluded entities and salaries paid to excluded individuals are not allowed.

Unlike other lists, however, the EPLS does not necessarily bar you from working with a party on the list. As long as the vendor does not need GSA approval nor reimbursement through federal program money, you may follow through with a contract, though you should review the arrangement with your legal counsel first.

The Office of Foreign Assets Control Sanctions Program

Sanctions from the Office of Foreign Assets Control (OFAC) don't specifically refer to healthcare-related compliance, but the screening policies still apply nonetheless. The result is that OFAC sanctions lists must be incorporated into an overall restricted party screening program.

OFAC operates as part of the U.S. Department of the Treasury and monitors financial activities with foreign policy and national security goals in mind. All U.S. dollar transactions anywhere in the world go through this office's purview. That means, all U.S. incorporated entities, their foreign branches, and any foreign subsidiaries they control are all expected to follow OFAC compliance, as well as foreign companies transacting in U.S. dollars.

While once the focus of financial institutions, OFAC has recently made some enforcement actions that pursue healthcare companies as well. OFAC screening involves the following multiple sanctions lists, including but not limited to:

- Specially Designated Nationals and Blocked Persons List (SDN)
- Consolidated Sanctions List
- Foreign Sanctions Evaders List
- Non-SDN Iran Sanctions Act List

These lists aim to identify risky individuals and groups from terrorists to narcotics traffickers. It's worth going through all of the OFAC sanctions programs on its official website to make sure you stay on the right side of the law.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act (FCPA) aims to prevent U.S. organizations from bribing foreign officials to advance business deals. In addition, it also lays out requirements for internal controls and record keeping that make it difficult to hide bribes.

While not exclusive to the healthcare industry, the FCPA nonetheless applies heavily to companies in this field for several reasons:

- **Extensive regulation:** The healthcare industry is heavily regulated, requiring extensive licensing, permits, and approvals throughout, resulting in many opportunities for corruption to take place. And since some countries have state-owned healthcare programs, the medical professionals involved are ultimately considered foreign officials.

- **Third-party procurement:** Healthcare relies greatly on the distribution of products and materials via third-party vendors and distributors. Any business relationship opens the door to illegal activities.

- **Urgency of the work:** Medical science involves some degree of urgency. Drugs, for example, can have expiration dates that require rapid movement of goods and services. Clearance at customs might be considered an obstacle.

It's also worth noting that some healthcare organizations choose to conduct clinical trials in developing nations with less capability to catch illegal activities. All of these factors put together emphasize the need to screen for illegal entities to mitigate costly violations.

Other Denied Parties Lists

The Drug Enforcement Administration (DEA), which handles illegal drug distribution within the U.S. and enforces the Controlled Substances Act, maintains its own excluded parties list that the healthcare industry must pay attention to.
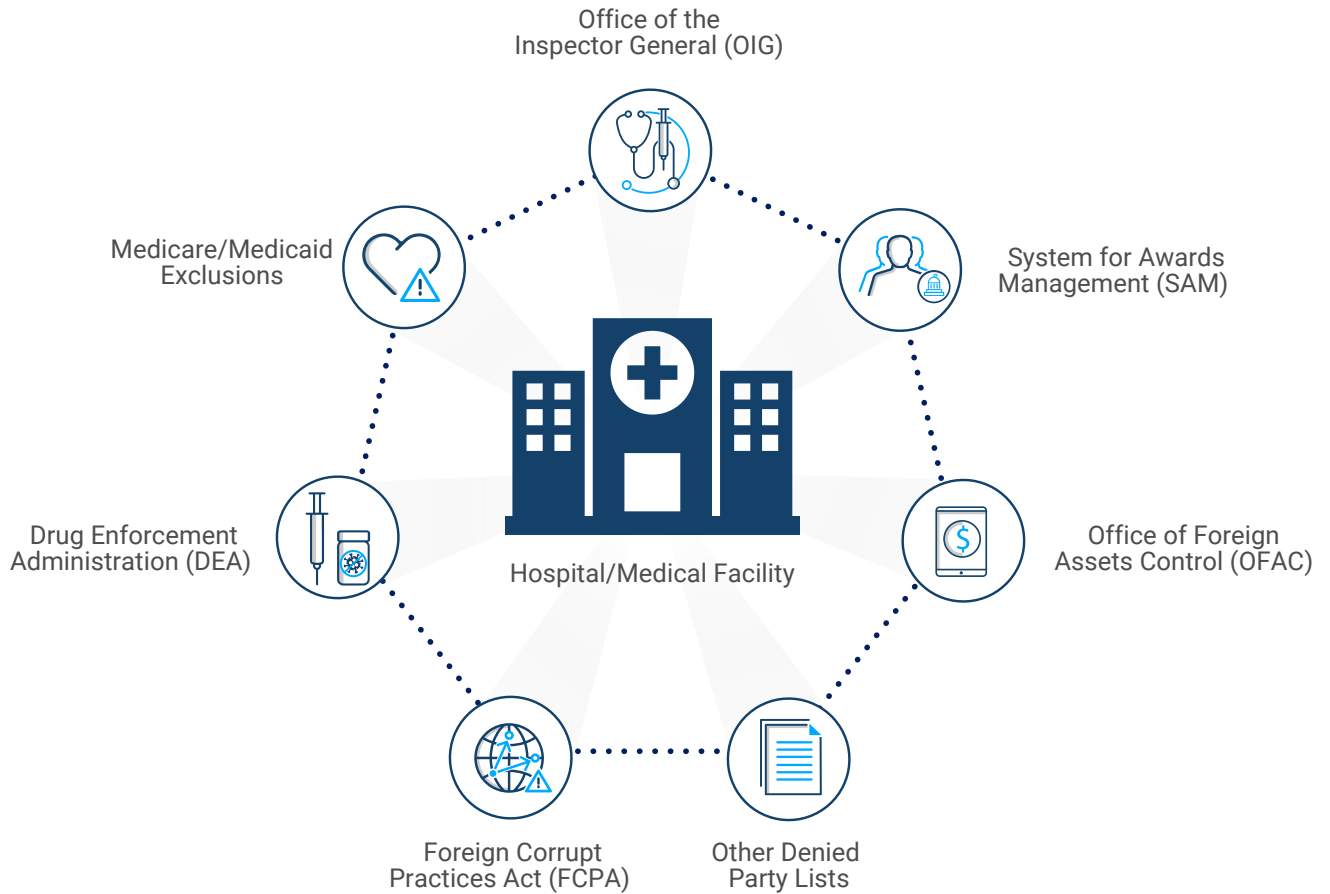
You must also consider individual state Medicaid exclusion lists. There is actually not one but 45 separate states, each with its own state Medicaid exclusion list. The Affordable Care Act has also effectively combined all these lists together by requiring that any entity barred from one list be banned from all state Medicaid programs.
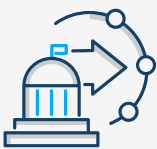
There are numerous screening lists to include in an organization's export compliance program.

Know Your Lists

There are numerous regulations that dictate what entities healthcare organizations cannot interact with. Take the following lists of excluded individuals and entities into account when designing your export compliance program.

Office of the Inspector General (OIG)

System for Awards Management (SAM)

Medicare/Medicaid Exclusions

Office of Foreign Assets Control (OFAC)

Drug Enforcement Administration (DEA)

Hospital/Medical Facility

Foreign Corrupt Practices Act (FCPA)

Other Denied Party Lists

Descartes can help mitigate your risk of interacting with excluded individuals and entities by streamlining your screening efforts.

Online Screening

Batch Screening

DESCARTES Compliance Solutions

Integrated Screening

Dynamic Rescreening

Step Two: Screen Everyone

To minimize your exposure to legal risk, screen all entities your organization is interacting with on an ongoing basis. These include:

- Employees
- Medical staff
- People and organizations involved in special projects and grants
- Those taking part in international programs
- Collaborating institutions
- Vendors and suppliers
- Buyers
- Resellers
- Contractors
- Visitors to your facilities
- People you meet in foreign travel

During your screening against the various exclusion lists, the search should also take into account spelling variations, hyphenations, nicknames, and aliases. Organizations should also have a policy and procedures in place for dealing with positive matches.

To maximize risk mitigation measures, organizations need to screen everyone they interact with.

Step Three: Screen Regularly

Ideally every month at least, conduct an exclusion screening process. The OIG actually recommends this frequency in its official bulletin, stating that, OIG updates the LEIE monthly, so screening employees and contractors each month best minimizes potential CMP (civil money penalty) liability. Other government agencies, such as OFAC, however, might update their watch lists on a daily basis.

The key reason for rescreening is that business relationships can span long periods of time, and that someone who is cleared to do business dealings today might not be tomorrow.

Step Four: Keep Up To Date with Screening Lists Changes

For the aforementioned OIG LEIE exclusions list, it's worth noting that it's your responsibility as a company to stay compliant with not only the OIG but also the database of excluded parties from each individual state. Since it's not a requirement for any state or the OIG to notify the public on new exclusions, do a complete checkup regularly and frequently to help ensure compliance.

The government in general makes it clear that businesses themselves are responsible for their own compliance, so do your due diligence and form a proactive exclusion screening policy and procedures. One of the best ways to keep compliance as a top corporate priority item is to designate a corporate champion which can take the form of an individual or a team of people.

Think also about setting up a screening workflow that includes reviewing positive matches, escalating selected cases to higher authority for further vetting, and storing compliance decisions with the associated rationale in the event of government audits.

Rescreening takes into account additions made to multiple official watch lists which collectively could occur daily. Having management-approved policies and procedures in place is the best way to keep up to date with screening list changes.

Step Five: Enable Collaboration Among Departments

Exclusion screening is too important a task in healthcare to be limited to the compliance officers, because there are many potential security gaps across an organization that need to be addressed. Engage different teams across the company to screen for exclusions as well. This will improve overall visibility, boosting collaboration in the process.

The best strategy is to implement a centralized compliance program to cover international operations, finance, human resources, data security, health and safety, among others. Only in this way can companies comply most effectively with healthcare and emerging compliance regulations and at the same time increase their profile as good corporate citizens.

The more visibility you can create around core compliance issues, the more aware your organization will be, improving your ability to detect and correct potential compliance issues.

Step Six: Leverage Technology for Optimal Compliance and to Enable Growth

It's clear that exclusion screening is an essential yet difficult process that every healthcare business must undergo. Not only must you make it a regular, consistent procedure, but you have to work with so many separate healthcare exclusion lists, which themselves may have overlapping entries.

If you want to streamline your denied party screening, using a centralized software platform can help your business ensure comprehensive and accurate export compliance checks. These services can identify entities present in relevant federal or state programs.

Proven technology solutions combined with automated screening also helps to address compliance requirements proactively and in a cost-effective manner, allowing you to focus more time on core business objectives.

The result, if done correctly, is not only compliance with the law, it's also about being in good standing with the government as well as other similarly-minded organizations, which in turn is an enabler of growth for the company.
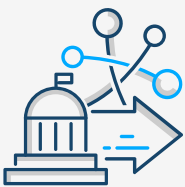
A company-wide approach to compliance significantly reduces the risk of breaching rules and regulations. Effectively screening against exclusions list is not just about compliance, it is also about enabling growth and meeting business targets.

Streamline Your Screening Efforts

Ensuring compliance screening across your entire organization can be a cumbersome, time-consuming task.
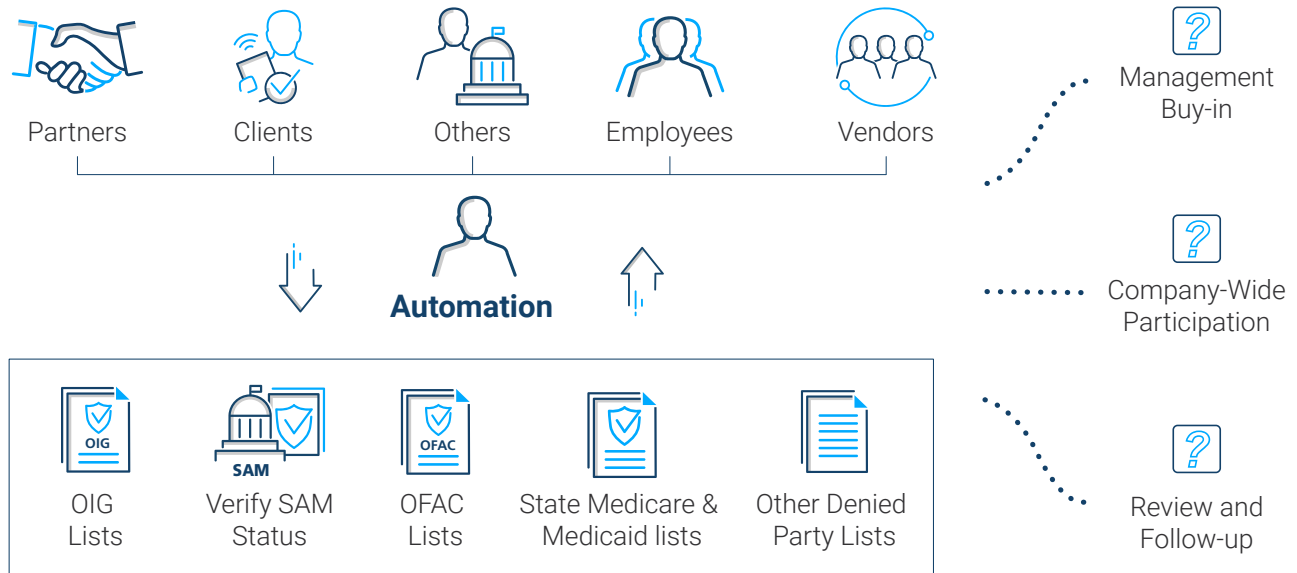
But exclusion screening doesn't have to be difficult if you adopt the right tools and technologies to streamline the process.

Whether you need real-time exclusion lists or comprehensive screening tools, streamlining the entire process is easy with Descartes excluded party screening solutions.

Mitigate Compliance Risk with Descartes

Governments maintain exclusion lists to prevent risky entities from interfering with domestic and international businesses. It's actually in the best interest of the healthcare company to pay attention to these lists, as excluded parties can pose a threat to national security, your intellectual property rights, the quality of your final product/service, and the safety of your patients.

Complying with exclusion lists can seem like a challenge at first glance. After all, the process includes multiple steps:

- Making sure you cover all the exclusion lists that apply to healthcare, such as the OIG's LEIE, the GSA's SAM, OFAC, and various others.
- Screening every employee and third-party partnership across your business and cross-checking them with these lists.
- Getting all your teams on board to contribute to an overall compliance program.

Exclusion screening doesn't have to be difficult if you adopt the right tools and technologies to streamline the process. Whether you need real-time exclusion lists or comprehensive screening tools, streamlining the entire process is easy with Descartes excluded party screening solutions.

Descartes can be deployed for automating integrated screening functions in ERPs, CRMs, or any other business systems. It can also be useful for online "ad hoc" research if the circumstances call for it.

Book a demo today and see why Descartes is the industry-leader in exclusion screening for Fortune 500 companies across all industries.

About Descartes Systems Group

Descartes (Nasdaq:DSGX) (TSX:DSG) is the global leader in providing on-demand, software-as-a-service solutions focused on improving the productivity, performance and security of logistics-intensive businesses. Customers use our modular, software-as-a-service solutions to route, schedule, track and measure delivery resources; plan, allocate and execute shipments; rate, audit and pay transportation invoices; access global trade data; file customs and security documents for imports and exports; and complete numerous other logistics processes by participating in the world's largest, collaborative multimodal logistics community. Our headquarters are in Waterloo, Ontario, Canada and we have offices and partners around the world.

Learn more at www.descartes.com and connect with us on LinkedIn and Twitter.

Uniting the People & Technology That Move the World.