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From hassle to habit: Tips for exclusion screening and monitoring

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“Don’t forget to take the face mask with you when you go to the store,” my mother reminded me before I went grocery shopping this morning. Because of the highly contagious coronavirus, face masks have now become an essential attire for going places. As a result, in addition to checking for keys and credit cards before leaving home, I have developed the habit of grabbing my face mask prior to stepping out the door. I am sure this new ritual can resonate with numerous people. Although bringing and wearing a face mask may not count as a cumbersome task, it is indeed a hassle and inconvenience to many. Nonetheless, in accordance with the guidance issued by public health officials and for the safety of ourselves and others, we must incorporate face masks into our daily checklist whether we like it or not—and for the most part it has successfully turned into a habit of ours, welcomed or not.

Regardless, this new change did prompt me to ponder some of our compliance measures, such as exclusion checks. To reduce the risk of employing an excluded person or engaging a debarred vendor, the actual screening and the ongoing monitoring must take place. But with all the high demands that our healthcare workers are facing nowadays and all the paperwork that is mandated by various laws, how do we know our frontline staff members are following the necessary steps? How can we help our teams develop a habit of checking exclusion lists so that the exclusion screening is not lost in the shuffle? And how can we ensure the monitoring is truly effective and consistent? What are the specific measures that can be implemented to enhance effectiveness and consistency?

This article aims to share some practical tips and concrete steps that our fellow healthcare providers can use to enhance their internal exclusion monitoring.

Regulatory requirements on exclusion screening

Federal law prohibits providers from contracting with excluded individuals/entities or billing for items supplied or services rendered by such parties, including any articles furnished and job duties performed that are directly or indirectly paid by federal healthcare programs in whole or in part.^[1] Pursuant to sections 1128 and 1156 of the Social Security Act, the Office of Inspector General under the U.S. Department of Health & Human Services has the authority to exclude individuals and entities from participating in federal healthcare programs.^[2] As of March 2021, there were more than 74,380 individuals and entities in the List of Excluded Individuals and Entities (LEIE), which is a database maintained by the Office of Inspector General of all currently excluded individuals and entities.^[3] In addition to the LEIE, other databases, such as the System for Award Management—another official government web portal that contains multiple information sources and comprehensive data on debarment actions taken by various federal governmental agencies—may also need to be checked to avoid violations.

Any healthcare providers that employ or contract with excluded persons or entities may be subject to liability and

other significant penalties, including denial of payment for items claimed or services rendered;^[4] civil monetary penalties of \$10,000 for each item claimed or service provided; treble damages (i.e., three times the amounts submitted to Centers for Medicare & Medicaid Services (CMS) for reimbursement);^[5] program exclusion of the company;^[6] loss of right to bill CMS for items claimed or services rendered;^[7] additional fines for filing false claims under the False Claims Act^[8] (e.g., penalties up to \$11,000 per claim and possible placement in a corporate integrity agreement);^[9] and criminal fines and/or incarceration.^[10]

Because the penalties are not mutually exclusive, they can quickly add up. To avoid any potential overpayment and liability, healthcare providers are advised to conduct exclusion checks on prospective employees and contractors prior to the employment or engagement and to continue the exclusion monitoring each month to reduce the potential risk of hiring an excluded employee or contractor.

Safeguard measures and preventive steps that organizations can take

Because healthcare providers are prohibited by law from employing or engaging an excluded individual or entity, it is imperative that organizations exercise their due diligence by screening their prospective employees and vendors and periodically checking the employee and vendor rosters against all applicable databases to ensure compliance. Knowing all the legal requirements is only the first step; developing appropriate measures and integrating them into daily operations as well as the compliance program are just as important as the knowledge about the regulations. In my opinion, exclusion check is a twofold process in practice (i.e., pre-hiring screening and ongoing monitoring). Much has been written by industry experts on the importance of conducting exclusion checks, so it is not foreign to healthcare providers when it comes to the basic elements of exclusion screening, such as the LEIE and frequency of checks, but the missing piece often falls on practice and practicality (i.e., how to ensure the occurrence of pre-hiring screening and ongoing systematic monitoring, materialize the theoretical instructions, and translate them into concrete measures and steps that are truly effective in tightening the process and closing the loop). Although there is no magic wand that makes all the rules disappear, there are simple steps and measures we can develop to help transform this hassle into a habit.

Policy review

Policies play an instrumental role in structuring an organization's practices and processes, as they provide guidance to employees so that tasks can be accomplished correctly and safely. Hence, it is no exaggeration to say that policies are the foundation of a company's operations. To meet the regulatory requirement, healthcare providers shall implement proper screening procedures to check all prospective and current employees and contractors (e.g., vendors, physician). Specifically, all of them must be checked against applicable exclusion databases prior to engaging their services and on a monthly basis thereafter, along with current employees and contractors. But the practical questions that should be asked are: Does your frontline staff know this? Is there a policy that formalizes and explains the requirement? Do you have procedures that clearly outline the steps that need to be followed? Who is responsible for conducting exclusion checks? When are exclusion checks expected to be completed? Are the procedures feasible in the midst of a pandemic? Is there a need to adjust measures accordingly? Below are some suggestions for your consideration:

- Review the policy at least annually and as frequently as needed. The expectation on pre-employment checks and monthly checks should be explicitly stipulated in your policy with no ambiguity. It is also critical to specify the time frame within which the exclusion checks must be completed.
- Streamline the process and designate the duty to a specific job position. Having a good working process helps reduce risk. Thus, it is crucial to translate theories into actions and fortify your exclusion screening

measures by standardizing protocols and streamlining processes. Moreover, delineation of responsibilities is equally important to the completion of any job tasks, because a task owned by everyone is a task for no one.

- Assess the clarity, viability, adaptability, and practicality of the procedures on a regular basis. Whether the current healthcare environment will affect the screening procedures should be taken into consideration, modifying them if needed. For instance, in an era of COVID-19, changes to the procedures may be warranted based on public health guidelines. Such changes should then be clearly communicated to responsible personnel.
- Mandate self-disclosure and timely notification. Within the same policy or in a separate one, it should require all employees and contractors to immediately disclose if they have become excluded by any federal or state governmental agency. Timely notification can allow healthcare providers to mitigate damages promptly and reduce liability. The policy should also provide that any misrepresentation or false statement by employees or vendors can lead to disciplinary actions and termination of contractual relationships, respectively.

Hiring practices and contracting processes

Whether your organization conducts checks manually or uses a third-party software program to track them, your frontline staff that is doing the hiring and contracting is the first line of defense, in that their actions, including accurate data entry of applicants' information into systems and documentation of the searches conducted, are vital to the effectiveness of the exclusion screening measures. Additionally, it is worth noting that other factors and obstacles can also negatively affect their hiring or contracting practices, which may jeopardize the efficacy of your organization's processes and measures. For example, staffing issues have long been a challenge faced by a wide range of healthcare providers, including long-term care facilities and hospitals. Having been hit hard by the pandemic, organizations now have the urgent need to hire people to replenish or supplement their already exhausted workforce. Inevitably, it could cause some hiring managers to skip necessary steps—whether intentionally or not—before bringing someone on board. Concerns arising from such questionable behavior include: Does your organization use a job application form or vendor form as a standard practice? Are there any exclusion-related questions on the forms? Does your organization require self-disclosure by applicants and vendors? Below for your reference are some ideas for evaluating your hiring and contracting processes.

- Assess questions on the job application forms and vendor credentialing forms. As part of the hiring and credentialing process, prospective employees and contractors should be required to disclose other names or aliases that they have used, confirm whether they have ever been excluded by any federal or state governmental agencies, and provide details if the answer is positive. Such questions need to be clearly written without legal jargon, thus limiting room for vagueness or different interpretation of the verbiage. The more information the organization has about a prospective employee or vendor, the more accurate the exclusion search results will be. In the case of a positive match, having comprehensive information will enable the organization to analyze the circumstances and issues involved therein.
- Include provisions in contracts that make applicants' and vendors' eligibility to participate in federal and state healthcare programs a condition of employment and a prerequisite to any contractual relationships. Incorporating such language and making it an essential term in contracts will help reduce and minimize the organization's exposure to potential civil damages, penalties, and criminal sanctions.
- Create a checklist for designated personnel. An easy-to-use checklist or cheat sheet serving as a quick reference guide can simplify processes for employees and keep tasks on track, especially when employees

are buried in the amount of paperwork they must complete on a daily basis.

- Verify the accuracy of information (e.g., individuals' and entities' names, Social Security/Taxpayer Identification numbers, addresses) and entry thereof. Any errors can skew the data and will be detrimental to the ongoing monitoring thereafter. Therefore, in order to generate accurate search results, all information must be correctly entered into systems. Having an additional review by a second person may easily solve the problem.
- Maintain documentation. Although exclusion checks may already be part of your hiring, credentialing, and contracting processes, documentation thereof is another significant piece that should not be overlooked. Without proper documentation, organizations would have a difficult time demonstrating all their efforts and due diligence. An easy fix will be to have responsible personnel print screen shots or web page results to evidence their searches.

Training and education

Merely having policies and procedures is not enough. If the designated personnel responsible for such screening are not aware of or familiar with the process, the policies and forms will have no actual impact on the organization's practice. Training and education is key to supporting the exclusion screening measures and ensuring compliance. There are some basic questions that should be asked: How often is your training on exclusion screening provided to employees? What is the staff turnover rate for the position responsible for conducting exclusion checks? Are your designated personnel familiar with the screening process and requirements? In the event of an exclusion match, do they know what to do? There are a variety of ways that can support and assist the operations and compliance teams with the enforcement efforts.

- Incorporate the topic into new-hire orientation, routine education plans, and training courses based on job roles and responsibilities. Add the subject to the new-hire orientation for personnel who are charged with conducting exclusion checks, such as human resources, procurement, and business development personnel. Training can heighten people's awareness and with time will gradually turn it into knowledge.
- Provide periodic training to responsible parties. It is vital for responsible parties to understand the legal ramifications, implications, and consequences for failure to comply. Depending on the turnover rate for the position, annual training may not be adequate, so it is highly recommended that periodic training on the subject be held to keep responsible parties abreast of the process and procedures in place. Countless research studies show that human habits are established through repetition. Elapsed time helps habits sink in and causes them to last. With frequent training, the intended behavior will become automatic or habitual—just like wearing a face mask before entering a store has become many people's habit.
- Organize awareness campaigns and quiz employees' understanding of the screening procedures. It would be a good idea to take the vitals of your screening process from time to time to gauge employee awareness and test their understanding of the subject, for there is a distinct difference between knowing the rules in theory and knowing how to actually apply them in practice. Because of the level of risk this type of violation can impose on organizations and the number of endeavors needed, periodic awareness campaigns can help employees recognize that regulations designed to ensure quality of care and safety are not going away and the good practices are here to stay. Failure to comply may result in dire consequences and will definitely put the entire organization at risk.

Periodic audits conducted by teams at different levels

To err is human. Even if your organization had a perfect process in place, it is people that execute and practice

the process. Unfortunately, there are no airtight measures. In reality, mistakes do happen, and it would be virtually impossible to prevent every incident from occurring, but there are methods that can be put in place to lower the likelihood of occurrence of these incidents, such as continual auditing and monitoring of your current practices.

- Perform compliance audits regularly. As one of the core compliance elements, auditing and monitoring is intended to assist compliance teams in carrying out their responsibilities to monitor risk areas, identify weak links in processes, verify the implementation of procedures, and ensure compliance with policies. As part of the safeguard measures, more frequent audits can be implemented company-wide to enhance ongoing monitoring and to detect potential issues early on. Since the LEIE is updated monthly,^[11] depending on the number of the employees and contractors your organization has, audits of comparable frequency are recommended.
- Collaborate with operations teams and step up monitoring efforts. Many organizations view compliance as an insurance policy that can reduce risk, ensure prosperity, and enhance reputation. However, it would be inadvisable to solely rely on the compliance team to achieve regulatory compliance. Rather, developing a well-thought-out process that promotes collaboration across departments and levels is the appropriate approach to take. For example, establishing a multilevel exclusion auditing and monitoring program that allows periodic reviews done by peers, regional employees, and corporate personnel may be an attainable strategy. It will not only make auditing and monitoring a routine practice, but also engage people from a variety of departments (e.g., human resources, procurement, legal) across multiple levels, thus increasing teams' comfort level with audits, raising awareness of regulatory requirements, and ultimately strengthening the organization's culture of compliance.

Final thoughts

The government's continued enforcement actions have demonstrated its focus on and commitment to ensuring no payment will be made for any item or service furnished, ordered, prescribed, or provided by an excluded person or entity.^[12] Given the potential liability and penalties, it is better to be safe than sorry (i.e., healthcare providers should implement reasonable safeguard measures to conduct and monitor exclusion checks). It might sound like a daunting task, but keep in mind that repetition forms habits, and practice breeds proficiency. Consistent processes and systematic monitoring will pay off and lead to long-lasting success.

I had never imagined that checking for my mask would be my habit, not in my wildest dreams, but the reality shows that face masks have undisputedly become an essential necessity of our daily life and been fully integrated into our new normal. Although it may be a long shot to think people would be zealous about doing exclusion screening, a face mask has sure come to be a must-have for my shopping excursions, and I wonder whether it will become a fashion accessory before long.

Takeaways

- Exclusion check is a twofold process (i.e., pre-hiring screening and ongoing monitoring); the practice and its practicality are often the missing piece.
- Developing appropriate exclusion screening measures and integrating them into daily operations are just as important as knowing about the regulations.
- Training and education are key to supporting the exclusion screening measures and ensuring compliance.
- Although there are no airtight measures, continual auditing and monitoring of current practices can lower

the likelihood of the occurrence of errors.

- Repetition forms habits and practice breeds proficiency; consistent processes and systematic monitoring lead to long-lasting successes.

1⁴² C.F.R. § 1003.102(a)(2) .

2 “Exclusion Authorities,” Office of Inspector General, U.S. Department of Health & Human Services, accessed March 16, 2021, <http://bit.ly/3lnxJCH>.

3 “LEIE Downloadable Databases,” Office of Inspector General, U.S. Department of Health & Human Services, accessed March 16, 2021, <http://bit.ly/33rrPXd>.

4⁴² U.S.C. § 1320a-7a .

5 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,” May 8, 2013, <https://bit.ly/315u9DI>.

6⁴² U.S.C. § 1320a-7a(a)(10) .

7⁴² C.F.R. § 424.535(a) .

8³¹ U.S.C. §§ 3729-3733 .

9 U.S. Department of Health & Human Services, Office of Inspector General, “Updated Special Advisory Bulletin.”

10⁴² U.S.C. § 1320a-7b .

11 “Exclusions FAQ,” Office of Inspector General, U.S. Department of Health & Human Services, accessed March 16, 2021, <http://bit.ly/38MbyRz>.

12⁴² C.F.R. § 1001.1901(b) .

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