



NEW FRAUD AND ABUSE SAFE HARBORS INCENTIVIZE EXPANSION OF WELLNESS PROGRAMS FOR HEALTHCARE WORKERS

The Stark Law and Anti-Kickback Statute are the two principal fraud and abuse laws in the United States impacting the healthcare industry today. The Stark Law prohibits physicians from making referrals for certain designated health services payable by Medicare or Medicaid to an entity with whom the physician or the physician's immediate family members have a financial interest. This law's primary purpose is to prevent such entities from submitting improper Medicare or Medicaid reimbursement claims for the healthcare services in question. Violations of the Stark Law can lead to substantial financial penalties and exclusions from federal healthcare programs.

Similarly, the Anti-Kickback Statute (or "AKS") criminalizes conduct for which any person knowingly and willfully offers, pays, solicits, or receives remuneration to induce or compensate a person to make referrals for items or services covered by Medicare, and other federal healthcare programs such as TRICARE and Medicaid. Violating the AKS can likewise result in substantial financial penalties, exclusion from federal healthcare programs, potential federal False Claims Act liability, and even imprisonment.

With little fanfare, Congress has expanded the categories of safe harbors for both fraud and abuse statutes by passing the Consolidated Appropriations Act, CAA, for 2023.¹ These new exceptions apply to wellness programs offered on or after December 29, 2022 and allow healthcare providers to administer certain mental and behavioral health programs to physicians and other clinicians. After serving on the frontlines during the pandemic, many healthcare professionals struggled with physical and emotional fatigue, which led to a spike in suicides among the profession. Recent studies illustrate that healthcare workers impacted by COVID showed increased rates of depression, insomnia, anxiety, and PTSD.² This new legislation will hopefully reverse these unfortunate trends.

The new Stark Law exception, found at 42 U.S.C. § 1395nn(e)(9), authorizes healthcare providers to offer bona fide mental health or behavioral health improvement or maintenance programs to physicians for the primary purpose of preventing suicide, improving mental health and resiliency, or providing training to promote the mental health and resiliency of such physicians.³ The program must consist of counseling, mental health services, a suicide prevention program, or a substance use disorder prevention and treatment program.⁴

These services must be evidence-based and conducted by a qualified health professional, and meet any other requirements imposed by the United States Secretary of Health and Human Services to protect against program or patient abuse.⁵ Additionally, programs must be set out in a written policy and approved before implementation by the governing body of the sponsoring entity.

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1. Consolidated Appropriation Act, 2023, H.R.2617, 117th Cong. (2022), available at <https://www.congress.gov/bill/117th-congress/house-bill/2617>.

2. Spoorthy MS, Pratapa SK, Mahant S. Mental health problems faced by healthcare workers due to the COVID-19 pandemic-A review. *Asian J Psychiatr.* 2020 Jun;51:102119. doi: 10.1016/j.ajp.2020.102119. Epub 2020 Apr 22. PMID: 32339895; PMCID: PMC7175897.

3. 42 U.S.C. § 1395nn(e)(9)(A) (Through Public Law 118-5, approved June 3, 2023)

4. 42 U.S.C. § 1395nn(e)(9)(A)(i) (Through Public Law 118-5, approved June 3, 2023)

5. 42 U.S.C. § 1395nn(e)(9)(A)(vi-vii) (Through Public Law 118-5, approved June 3, 2023)

Other requirements of the written policy include a description of the evidence-based support for the design of the program, the estimated cost of the program, identification of personnel conducting the program, and a summary of their qualifications, and the method by which the entity will evaluate the use and success of the program. Finally, all the aforementioned requirements must be updated in advance of substantial changes to the operation of the program.⁶

Notably, the new Stark Law exception is not applicable to all healthcare providers. For a program to qualify under the exception, it must be offered at a hospital, ambulatory surgical center, rural emergency hospital or health clinic, skilled nursing facility, or similar entity, as determined by the United States Secretary of Health and Human Services.⁷ These providers are required to have a full medical staff and must offer the program to all physicians who practice in the geographic area served by such entity, including physicians who hold bona fide appointments to the medical staff of such entity or otherwise have clinical privileges at such entity.⁸ Programs must be offered on the same terms and conditions to all such physicians and without regard to the volume or value of referrals or other business generated by a physician for the entity and must consist of counseling, mental health services, a suicide prevention program, or substance use disorder prevention and treatment program.⁹

The new exception to the Anti-Kickback Statute can be found at 42 U.S.C. § 1320a-7b (b)(3)(L), and essentially matches the Stark Law wellness program exception but includes clinicians along with physicians while excluding rural health clinics.¹⁰ The AKS also requires that these program offer counseling, mental health services, suicide prevention, or substance use disorder treatment.¹¹ These programs require a written policy approved by the governing body of the organization offering it.¹² The policy should include program details, evidence-based support, estimated costs, qualified personnel, and evaluation methods.¹³ The program, must be available to all physicians and clinicians in the area without any conditions based on referrals or business generated.¹⁴ Similar to the Stark Law, the program should be evidence-based, conducted by qualified professionals, and adhere to regulations set by the United States Secretary of Health and Human Services to prevent abuse.¹⁵

The creation of these new exceptions offers the healthcare industry important new avenues to enhance the mental health, physical health, and overall well-being of healthcare workers. This, in turn, can naturally lead to improved patient outcomes and reduced healthcare costs. In light of the government's recent expansion of fraud and abuse safe harbors, we recommend that clients seeking to enter into transactions with eligible entities be proactive in their approach. Our Firm's Healthcare Advisory Team welcomes the opportunity to consult with providers to ensure compliance with these and other ever-changing healthcare regulations.

“...THESE NEW EXCEPTIONS OFFERS THE HEALTHCARE INDUSTRY IMPORTANT NEW AVENUES”

6. 42 U.S.C. § 1395nn(e)(9)(A)(iii) (Through Public Law 118-5, approved June 3, 2023)

7. 42 U.S.C. § 1395nn(e)(9)(B) (Through Public Law 118-5, approved June 3, 2023)

8. 42 U.S.C. § 1395nn(e)(9)(A)(iv) (Through Public Law 118-5, approved June 3, 2023)

9. 42 U.S.C. § 1395nn(e)(9)(A)(v) (Through Public Law 118-5, approved June 3, 2023)

10. Since operation within a safe harbor is not required for compliance with the Anti-Kickback Statute, a wellness program offered by a rural health clinic that complies with all other requirements of the Anti-Kickback Statute wellness program exception would seem unlikely to violate the statute, absent an intention to induce referrals.

11. 42 U.S.C. § 1320a-7b (b)(3)(L)(i)(I)

12. 42 U.S.C. § 1320a-7b (b)(3)(L)(i)(III)

13. 42 U.S.C. § 1320a-7b (b)(3)(L)(i)(III)

14. 42 U.S.C. § 1320a-7b (b)(3)(L)(i)(II)

15. 42 U.S.C. § 1320a-7b (b)(3)(L)(i)

This summary and legal alert is an overview of the new developments in the health care industry. It is not intended to be, and should not be construed as, legal advice for a specific factual situation.



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