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Health Law **Pulse**



PROPOSED REGULATIONS DELINEATE SCOPE OF SAFE HARBOR FOR FEDERALLY QUALIFIED HEALTH CENTERS UNDER THE ANTI-KICKBACK STATUTE

On July 1, 2005, the Department of Health and Human Services (the Department) published a proposed rule that would establish a “safe harbor” allowing medical providers and suppliers to provide assistance to Federally Qualified Health Centers (FQHCs) without violating the anti-kickback statute. The new safe harbor would permit ‘transfers’ “of goods, items, services, donations, loans, or combination thereof,” by individuals and entities to certain FQHCs, so long as such transfers satisfy all eleven standards of the proposed safe harbor. The basic provisions of the proposed safe harbor are as follows:

- The safe harbor would only apply to “transfers” made to FQHCs receiving grants under Section 330 of the Public Health Service (PHS) Act (either directly or under contract with a direct grant recipient).
- The ‘transfer’ must be made pursuant to a written agreement clearly identifying the particular assistance and the quantity of such assistance that would be provided to the FQHC.
- The arrangement would have to contribute meaningfully to the purpose of the section 330 grant program (i.e., improving medical services provided to underserved populations). FQHCs must use a consistent approach in determining whether the arrangement would further this purpose and must periodically (at least once a year) reevaluate these determinations. The FQHCs must document the basis for their decisions and make the documentation available to the Department upon its request.
- The agreement must preserve the patient’s freedom of choice and the independent medical judgment of the FQHC staff. Toward this end, FQHCs must notify patients of their freedom to choose any willing provider or supplier. They would also be required to disclose the existence of any arrangements protected under the safe harbor, either upon request or whenever a patient is referred for “separately billable items or services” to a party to one of these arrangements. FQHCs may not enter into arrangements which impose an obligation on the FQHC to either refer patients to or deal exclusively with a particular provider or supplier.
- Providers or suppliers who enter into transactions covered by the safe harbor would be required to fairly and evenly treat FQHC patients. While providers and suppliers may set “reasonable limits” on the amount of services and goods they would provide, they must accept referrals without discrimination on the basis of ability to pay or access to third-party reimbursement.

It should be noted that while most of the proposed safe harbor sets forth standards for

conduct on the part of FQHCs, it is the transactions themselves that either qualify or do not qualify for the safe harbor's protection. Therefore, compliance with the proposed safe harbor should be equally of concern to providers and suppliers who provide assistance to FQHCs as well as to the FQHCs themselves.

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