or limit clinical services directly or indirectly violates the statute.

We are aware that a number of hospitals are engaged in, or considering entering into, incentive arrangements commonly called ''gainsharing.'' While there is no fixed definition of a ''gainsharing'' arrangement, the term typically refers to an arrangement in which a hospital gives physicians a percentage share of any reduction in the hospital's costs for patient care attributable in part to the physicians' efforts. We recognize that, properly structured, gainsharing arrangements can serve legitimate business and medical purposes, such as increasing efficiency, reducing waste, and, thereby, potentially increasing a hospital's profitability. However, the plain language of section 1128A(b)(1) of the Act prohibits tying the physicians' compensation for services to reductions or limitations in items or services provided to patients under the physicians' clinical care.[65]

In addition to the CMP risks described above, gainsharing arrangements can also implicate the anti-kickback statute if the cost-savings payments are used to influence referrals. For example, the statute is potentially implicated if a gainsharing arrangement is intended to influence physicians to ''cherry pick'' healthy patients for the hospital offering gainsharing payments and steer sicker (and more costly) patients to hospitals that do not offer gainsharing payments. Similarly, the statute may be implicated if a hospital offers a cost-sharing program with the intent to foster physician loyalty and attract more referrals. In addition, we have serious concerns about overly broad arrangements under which a physician continues for an extended time to reap the benefits of previously-achieved savings or receives cost-savings payments unrelated to anything done by the physician, whether work, services, or other undertaking (*e.g.,* a change in the way the physician practices).

Wherever possible, hospitals should consider structuring cost-saving arrangements to fit in the personal services safe harbor. However, in many cases, protection under the personal services safe harbor is not available because gainsharing arrangements typically involve a percentage payment (*i.e.,* the aggregate fee will not be set in advance, as required by the safe harbor). Finally, gainsharing arrangements may also implicate the Stark law.

[65] A detailed discussion of gainsharing can be found in our July 1999 Special Advisory Bulletin titled ''Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries,'' available on our Web page at *http://oig.hhs.gov/fraud/docs/altersandbulletins/gainsh.htm.*

D. Emergency Medical Treatment and Labor Act (EMTALA)

Hospitals should review their obligations under EMTALA (section 1867 of the Act) to evaluate and treat individuals who come to their emergency departments and, in some circumstances, other facilities. Hospitals should pay particular attention to when an individual must receive a medical screening exam to determine whether that individual is suffering from an emergency medical condition. When such a screening or treatment of an emergency medical condition is required, it cannot be delayed to inquire about an individual's method of payment or insurance status. If the hospital's emergency department (ED) is ''on diversion'' and an individual comes to the ED for evaluation or treatment of a medical condition, the hospital is required to provide such services despite its diversionary status.

Generally, hospital emergency departments may not transfer an individual with an unstable emergency medical condition unless a physician certifies that the benefits outweigh the risks. In such circumstances, the hospital must provide stabilizing treatment to minimize the risks of transfer. Further, the hospital must ensure that the receiving facility has available space and qualified personnel to treat the individual and has agreed to accept transfer of that individual. Moreover, certain medical records must accompany the individual and a hospital that has specialized capabilities or facilities must accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual.

A hospital must provide appropriate screening and treatment services within the full capabilities of its staff and facilities. This includes access to specialists who are on call. Thus, hospital policies and procedures should be clear on how to access the full services of the hospital, and all staff should understand the hospital's obligations to individuals under EMTALA. In particular, on-call physicians need to be educated as to their responsibilities under EMTALA, including the responsibility to accept appropriately transferred individuals from other facilities. In addition, all persons working in emergency departments should be periodically trained and reminded of the hospital's EMTALA obligations and hospital policies and procedures designed to ensure that such obligations are met.

For further information about EMTALA, hospitals are directed to: (i) The EMTALA statute at section 1867 of the Act; (ii) the EMTALA statute's implementing regulations at 42 CFR part 489; (iii) our 1999 Special Advisory Bulletin on the Patient Anti-Dumping Statute (64 FR 61353; November 10, 1999), available on our Web page at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/frdump.pdf;* and (iv) CMS's EMTALA resource Web page located at *http://www.cms.gov/providers/emtala/emtala.asp.*

E. Substandard Care

The OIG has authority to exclude any individual or entity from participation in Federal health care programs if the individual or entity provides unnecessary items or services (*i.e.,* items or services in excess of the needs of a patient) or substandard items or services (*i.e.,* items or services of a quality which fails to meet professionally recognized standards of health care).[66] Significantly, neither knowledge nor intent is required for exclusion under this provision. The exclusion can be based upon unnecessary or substandard items or services provided to any patient, even if that patient is not a Medicare or Medicaid beneficiary.

We are mindful that the vast majority of hospitals are fully committed to providing quality care to their patients. To achieve their quality-related goals, hospitals should continually measure their performance against comprehensive standards. Medicare participating hospitals must meet all of the Medicare hospital conditions of participation (COPs), including without limitation, the COP pertaining to a quality assessment and performance improvement program at 42 CFR 482.21 and the hospital COP pertaining to the medical staff at 42 CFR 482.22. Compliance with the COPs is determined by State survey agencies or accreditation organizations, such as the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association. In addition, hospitals should develop their own quality of care protocols and implement mechanisms for evaluating compliance with those protocols.

In reviewing the quality of care provided, hospitals must not limit their review to the quality of their nursing and other ancillary services. Hospitals must monitor the quality of medical

[66] *See* section 1128(b)(6)(B) of the Act, which is available through the Internet at *http://www4.law.cornell.edu/uscode/42/1320a-7.html.*