General Information: Bans on self-referral (the Stark Act) and antikickback provisions relate to a concern that those with the power to refer will enrich themselves with marginally necessary or unnecessary procedures or supplies, thus increasing the cost of health care to the consumer and any third-party payors, including the government.

Stark Act = Prohibition for physician referrals/conflict of interest

Stark Act Provisions:		Difference with proposed or current MT statute(s)	Implications for Montana approach
Who is affected	Physicians if they or an immediate family member have a financial relationship with entity to which referring	• Current Montana law on economic credentialing expands to include partner or employee of physician • Proposed LC38 expands to include disclosure of relationships for all referring health care providers, owners as well as employed who may be making referrals. The proposal would not ban referrals just make consumers aware that a referral may relate to a conflict of interest.	• Conflict of interest issues affect: 1. Economic credentialing issue between hospitals and physicians. LC38, Section 10 2. All health care providers who may have a conflict that unduly influences professional judgment when referring a patient. LC38, Sections 6-7-8 • LC 38 provisions are intended to permit conflicts, unless they are recurring and unduly influencing a patient referral. Requires disclosure of conflict and uses antikickback language to restrict financial ties.
Key Definitions	Bona fide employment relationship: • Employment is for identifiable services; • Remuneration is consistent with fair market value and not determined in a manner that takes into account directly or indirectly the volume or value of referrals by the referring physician and is part of a commercially reasonable agreement even if no referrals are made.	• Proposed LC38 does not provide exclusions under disclosure section for anyone. Covers all health care providers, regardless of ownership or employment who have a connection with a health care provider or health care facility to which a patient is being referred. [section 1] • Exclusions from "remuneration" in the antikickback section [section 3: 1) written contracts let in an open-bid process, provided discounts/reductions disclosed as provided by rule after award; 2) fair market value payments including bonuses if not based on specific volume or business based on referrals paid by employer or group practice to the extent allowed under 42 U.S.C. 1320a-7b 3) vendor payments to purchasing agent as specified in 1320a-7b(b)(3)(C) 4) waivers, reductions, amounts paid as permitted under 1320a-7b(b)(3)(D) through (H) to entities listed in federal law 5) written, fair market value agreements	• Section 1 expands disclosure to employment for all health care providers. • Section 3 –covering all payors not just Medicaid and Medicare (children and family services) broadens those subject to kickback provisions. • Complaints about Section 3: 1) The MT Association of Physical Therapy contends that the exclusions in the antikickback statute (see that law below) would strip most meaning from this section. 2) Roy Kemp with the Quality Assurance Division at DPHHS said this would require more expertise on both the Antikickback and Stark laws (currently regulated at the federal and not the state level) and more FTEs in the fiscal note. Just putting in references to the many pages of federal guidance ---(Stark alone keeps coming out with CFRs numbering 50-or-more pages at each iteration and there have been at least 2 since September 2007) ---does not solve the problem because of the federal law exclusions. On the other hand, there's a question of who is watching this at the federal level. • Other Issues (see below): Removing this subsection would not impact the ability of health care facilities to complain about

		between health care facilities and physicians allowed under exceptions for 42 U.S.C. 1395nn(e)(1) through (8)	conflict of interest among health care providers.
	Designated Health Services (DHS) The designated health services are a key part of the physician self-referral ban: 42 U.S.C. 1395nn(a)(1) Except as provided… (a) the physician may not make a referral to the entity for the furnishing of designated health services… " Designated Health Services: A) clinical laboratory services B) physical or occupational therapy C) radiology or other diagnostic services; D) radiation therapy services; E) furnishing of durable medical equipment F) furnishing of parenteral and enteral nutrition nutrients, supplies, and equipment G) home health services H) furnishing of prosthetics, orthotics, and prosthetic devices	LC38 would encompass services offered by any of the following (for Section 1 in terms of referrals, if they refer and have an investment, employment or contractual interest or for Section 3 in terms of kickback prohibitions, minus exclusions): • physicians • dentists • podiatrists • pharmacists • nurses • nursing home administrators • optometrists • physical therapists • chiropractors • acupuncturists • radiologic technologists • speech language pathologists and audiologists • hearing aid dispensers • psychologists • physician assistants • dieticians • social workers • professional counselors • occupational therapists • nutritionists • naturopathic physicians • direct-entry midwives • respiratory care practitioners • clinical laboratory science practitioners • addiction counselors • athletic trainers • other diagnostic services (as defined)	LC38 would not ban self-referral but would require all health care providers licensed under Title 37 or facilities licensed under Title 50 as those who would have to disclose financial/employment interests if they had any type of referral (not just DHS). Also, any health care provider receiving any type of payment would be covered by the antikickback provision (section 3) unless given an exception. In addition, diagnostic services receiving Medicare or Medicaid would be included as well as referrals for prescribed supplies or services. Roy Kemp of DPHHS provided this list of services or facilities covered via a Title 37 licensee or that are not otherwise licensed: Facilities I am aware of that receive no [facility] license because of the Title 37 exception or the lack of authority include: urgent care centers, plastic surgery clinics, urology centers, pain management clinics, eye lasic surgery centers, home care services, most imaging centers, rural health clinics, federally qualified health clinics, bariatric surgery centers, cancer or oncology centers, linear accelerators, nephrology centers, lithotripsy services, most birthing centers (2 as outpt cntrs for primary care because of Medicaid pymt) sleep labs, neurology clinics, physical therapy clinics, naturopathic services, chiropractic centers, and any federal facility such as the VA hospital, or HUD retirement homes, to mention a few (9/12/2007 email) Anything connected with a Title 37 licensee would be covered plus the imaging centers and diagnostic facilities (newly defined). Home care services may not be covered unless provided by a Title 37 health care provider. I'm not sure about linear accelerators unless they are operated by Title 37 licensee. Federal facilities' MT-licensed health care providers would be affected but non-MT licensed providers would not.
	Financial Relationship: A) ownership or investment interest, except as provided in subsections c &d (investment securities, etc., or 1) hospitals in Puerto Rico; 2) DHS	LC38 has 3 places that refer to a financial relationship: • Section 1 talks about investment, employment, or contractual interest related to a referral. These terms are not defined.	Stark's Financial Relationship exception for DHS in rural areas applies to Montana because all of Montana meets the definition of rural area in 1395ww(d)(2)(D) of Stark--meaning any area outside a population area of more than 1 million people. (and substantially all of the DHS are furnished to

	furnished in a rural area and not a specialty hospital) and 3) investment is in whole hospital and the entity is not a specialty hospital. B) a compensation arrangement between the physician (or immediate family member) and an entity, except as provided in subsection (e) (e) covers: 1) rental of office space & equipment 2) bona fide employment relationships; 3) personal service arrangements including physician incentive plans; 4) remuneration unrelated to DHS C) general exceptions include: 1) physician services provided personally or under the personal supervision of another physician in the same group practice as the referring physician; or 2) in-office ancillary services (excluding a) durable medical equipment other than infusion pumps and b) parenteral and enteral nutrients, equipment and supplies) that are furnished personally or under personal supervision or within the group practice, in a building where services provided unrelated to the furnishing of DHS or in a building related to the group practice OR that are billed by the group practice or an entity wholly owned by the physician or group practice, or 3) furnished by an organization with a contract to provide services to individuals enrolled with the organization or having a prepaid plan or that is a	• Section 7 in the definition for Title 37 purposes of conflict of interest as it relates to investment, employment, or contractual interest that is the beneficiary of a referral. This definition is used for the unprofessional conduct references under Sections 8 & 9. • Section 11 – the economic credentialing statute, reference conflict of interest for physicians who may not be allowed to sit on a hospital board, etc. Subsection (3) defines the conflict as a financial interest if a person directly or indirectly owns greater than a 5% ownership interest in a health care facility licensed under this title that offers similar services as a hospital licensed under this title. By making the reference only to facilities licensed under Title 50 and putting the percentage limit in, there is no need to reference stock exchanges, as other state laws do. (see column at right) There may be more specificity required regarding bonds, debentures, etc., as indicated at right	individuals residing in the rural area). Other states have separately listed something similar to the following in their referral statutes (most of which ban referrals with a self-interest): Florida: 456.053(3)(k) “Investment interest” means an equity or debt security issued by an entity, including, without limitation, shares of stock in a corporation, units or other interests in a partnership, bonds, debentures, notes, or other equity interests or debt instruments. The following investment interests shall be excepted from this definition: (1) An investment interest in an entity that is the sole provider of designated health services in a rural area; (2) An investment interest in notes, bonds, debentures, or other debt instruments issued by an entity which provides designated health services, as an integral part of a plan by such entity to acquire such investor’s equity investment interest in the entity, provided that the interest rate is consistent with fair market value, and that the maturity date of the notes, bonds, debentures, or other debt instruments issued by the entity to the investor is not later than October 1, 1996. (3) An investment interest in real property resulting in a landlord-tenant relationship between the health care provider and the entity in which the equity interest is held, unless the rent is determined, in whole or in part, by the business volume or the profitability of the tenant or exceeds fair market value; or (4) an investment interest in an entity which owns or leases and operates a hospital licensed under chapter 395 or a nursing home facility licensed under chapter 400. (Definition of rural is an area with 100 people /sq. mile. No place in Montana has more than 50 people/sq. mile (Yellowstone County was at 49.1/sq. mi. in 2000 census).

	qualified HMO or Medicare+Choice organization.		
	Physician Incentive Plan • A compensation arrangement between a physician/physician group and an entity that may directly or indirectly result in reduced or limited services for individuals enrolled with entity. • Takes into account directly or indirectly the volume or value of referrals or other business generated if no specific payment made as an enducement. Addresses financial risk and requires reporting to the DHHS Secretary.	No provision for this, except possibly within the exclusions allowed under Section 3(2)(e) that reference Stark Act	Unclear what the implications would be for this.
Exceptions/ Exclusions	• "Bona Fide Employment" • "Financial Relationships" • "Physician Incentive Plans" Common language for many of the exclusions is: • "physician is not required to refer patients to the hospital" (physician recruitment) • Contract required and no specific reference to referrals • Physician Incentive Plans appear to be effort to get doctors to limit referrals of Medicare or Medicaid patients to hospitals as a cost-control measure but rules regulate through financial risk assessment. (reporting required)	LC38 – Section 1 has no exceptions Section 3 – uses antikickback statute exceptions and for physicians the Stark Exceptions.	Relying on federal law exclusions would complicate the enforcement for Title 37 boards/department and for the Quality Assurance Division for the Section 5 enforcement link to unprofessional conduct.

Antikickback Act, 42 U.S.C. 1320a-7b

		Difference with proposed MT statute	Implications for Montana approach
Who is affected	Any individual who receives directly or indirectly, overtly or covertly, in cash or in kind in return for referring a person for the "furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program". Or "in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, etc."	3) Proposed version expands to include blanket ban on referrals, no matter the payor.	4) An estimated 50 MT optometrists in independent offices currently invest in a medical supply facility for eyeglasses. If unable to do that, they would be less able to compete with large discount stores (like Shopko, Costco), which often hire optometrists who don't then have the investment relationship in the eyeglass supplies although their employer may have that investment.
Key Definitions	Bona Fide Employment	(see Stark version above)	
	Federal Health Program	The federal health care program covers Medicare, Medicaid, and any state health care program defined under 1320a-7h), which includes child and family services and foster care	
	Financial Relationship	(see Stark version above)	
Exceptions (not inclusive here)	"Bona Fide Employer"		
	Discounts if properly disclosed		
	Written contract via purchasing group [sub(C)]or risk-sharing arrangement [sub(F)]		
	Rural health center entities if maintain or increase availability/quality		

DRAFT July 22, 2008