

## Explanation of Changes to LC38 July 22 version

Disclosure	Former Version (April 29 draft)	Revised Version (July draft)
Section 1 Sub (1)	Section 1. (1) It is public policy for the state of Montana that a patient receive from health care providers information that allows the patient to make informed decisions not only relating to their medical conditions but also to the financial or quality aspects of their health care decisions.	Section 1. (1) Stayed same
Section 1 Sub (2)	(2) (a) As related to the financial or quality aspects of the health care decisions, a health care practitioner shall disclose, except as provided in subsection (2)(b), to a patient: <ul style="list-style-type: none"> <li>(i) any investment interest in a health care facility; or</li> <li>(ii) an employment contract, employment agreement, or contract-for-hire arrangement with a health care facility.</li> </ul> (b) The provisions of subsection (2)(a) do not apply to a patient seeking emergency care.	(2) (a) Except as provided in subsection (3), a health care provider who makes referrals and who has an investment, employment, or contractual interest related to that referral shall disclose the investment, employment, or contractual interest in writing of 100 words or less to an existing or prospective patient or client. <ul style="list-style-type: none"> <li>(b) The disclosure required in subsection (2)(a):               <ul style="list-style-type: none"> <li>(i) must be in at least 10 point type and on a separate piece of paper from the general paperwork received by a patient or a client at the initiation of a visit;</li> <li>(ii) must be posted in a conspicuous place in the office or facility;</li> <li>(iii) must be provided at the initiation of a visit or, preferably, at the time of the referral; and</li> <li>(iv) may request a patient's or a client's signature.</li> </ul> </li> <li>(c) This subsection (2) does not prohibit a health care provider from recommending a preferred health care provider when making a referral.</li> </ul>
Explanation of changes Sub (2)	<ul style="list-style-type: none"> <li>• Changed word practitioner to provider for consistency.</li> <li>• Limited application to “health care provider who makes referrals and who has an investment, employment, or contractual interest related to that referral”.</li> <li>• Added word client to reflect that some health care providers (hearing aid examiners) have “clients” more than “patients”.</li> <li>• Moved exclusion of (2)(b) to new (3) so that subsection 2 would be about process and clarify “when” and “how” the disclosure can be made. The process in former (sub 3) was revised and added to but the required list of referrals was removed. Additions:               <ul style="list-style-type: none"> <li>▶ specify at least 10 point type &amp; a separate piece of paper from the general paperwork received by a patient or a client at the initiation of a visit;</li> <li>▶ require posting in a conspicuous place in the office or facility;</li> <li>▶ describe when to be provided and state preference of time of the referral; and</li> <li>▶ note that a patient's signature may be required.</li> </ul> </li> <li>• Allows preference to be stated in making a referral.</li> <li>• Omits reference to oral or written information about freedom to choose. (This is put into sample disclosure.)</li> <li>• Omits assurance of patient not being treated differently depending on choice.</li> </ul>	
Section 1 Sub (3)	(3) (a) A health care practitioner who makes referrals to a health care facility shall: <ul style="list-style-type: none"> <li>(i) provide written notification of under 100 words disclosing the investment or employment interest to the patient when making a referral to a facility in which the health care practitioner has an investment or employment interest;</li> <li>(ii) provide a list of alternative licensed health care facilities or health care providers if they are available;</li> </ul>	(3) Subsection (2) does not apply to a patient receiving emergency care or to a patient admitted as an inpatient of a hospital, a critical access hospital, or an outpatient center for surgical services, except that prior to the discharge of an inpatient who needs home health care or skilled nursing that patient must be given appropriate referral information, as required under 42 CFR 482.43.

	<p>(iii) inform the patient, either orally or through written means, that the patient has freedom to choose the health care provider or facility to obtain services; and</p> <p>(iv) assure the patient that the referring health care practitioner will not treat the patient differently depending on the patient's choice of health care practitioner or facility. not prevent a health care</p> <p>(b) This subsection (3) does practitioner from stating a preference when making a referral.</p>	
Explanation of changes Sub (3)	<ul style="list-style-type: none"> <li>• Former Sub(3) now part of (2)(a) as part of process realignment. New subsection (3) is formerly subsection (2)(b) but it's expanded to include exceptions for inpatients of hospitals, critical access hospitals, or outpatient surgical centers.</li> <li>• Provides exception for patient being discharged who must be given appropriate referral information under federal rule.</li> </ul>	
Section 1 Sub (4)	(no former sub (4))	<p>(4) The disclosure required in subsection (2) may be similar to the following statement:</p> <p><i>During the course of your relationship with this health care provider, you may be referred to another health care provider or health care facility with which your referring health care provider has an investment, employment, or contractual interest. Your referring health care provider has an (investment, employment, contractual) relationship with _____ (facility or health care provider) and an (investment, employment, contractual) relationship with _____ (facility or health care provider).</i></p> <p><i>You, as a patient or client, have freedom to choose among health care providers and health care facilities.</i></p>
Explanation of changes Sub (4)	Provides a sample disclosure statement.	
Section 1 Sub (5)	<p>Definitions formerly were in Section 2. Those were:</p> <p>(3) For the purposes of [section 1] and this section, the following definitions apply:</p> <p>(a) A "health care practitioner" is a person licensed under Title 37, chapters 3 and 4, 6 through 17, 20 through 28, 34 through 36.</p> <p>(b) A "referral" is a written or oral order from a health care practitioner to a patient or client for health care services, including:</p> <p>(i) the forwarding of a patient to another health care practitioner or to a health care facility licensed under Title 50 or operated by a health care practitioner under Title 37 or to an entity that provides or supplies health services or health care supplies;</p> <p>(ii) a request or establishment of a plan of care that includes the provision of health services or health care supplies; and</p> <p>(iii) the information in [section 1(2)].</p>	<p>(5) For the purposes of [sections 2 and 3 and this section], the following definitions apply:</p> <p>(a) "Diagnostic services" mean magnetic resonance imaging, nuclear medicine, angiography, arteriography, computed tomography, positron emission tomography, digital vascular imaging, bronchography, lymphangiography, splenography, ultrasound, electroencephalography, electrocardiography, nerve conduction studies, and evoked potentials.</p> <p>(b) "Health care provider" is a person licensed under chapters 3 and 4, 6 through 17, 20 through 28, and 34 through 36, or a provider of diagnostic services who receives a medicare or medicaid payment under Titles XVIII or XIX of the Social Security Act, respectively.</p> <p>(c) "Referral" is a written or oral order from a health care provider to a patient or client for health care services outside of a routine office exam, including:</p> <p>(i) the forwarding of a patient or a client to another health care provider</p>

		with the same or a different license, to a diagnostic facility that receives medicare or medicaid payments under Titles XVIII or XIX of the Social Security Act, respectively, or to a health care facility licensed under Title 50 or operated by a health care provider licensed under this title; or (ii) a request or establishment of a plan of care that includes the provision of prescribed health services or prescribed health care supplies.
Explanation of changes (Sub 5)	<ul style="list-style-type: none"> <li>• Definitions now apply to 3 new sections, to be codified in Title 37, regarding licensing boards.</li> <li>• Added to definitions: <ul style="list-style-type: none"> <li>▶ diagnostic services (taken from Florida statute).</li> <li>▶ changed health care practitioner to health care provider</li> <li>▶ added diagnostic services plus references to Medicare and Medicaid regarding diagnostic facilities so that the referral is being made to a facility that has been vetted by federal payors.</li> </ul> </li> <li>• Under referral definition added “outside of a routine office exam” and allowed same or different license, because same license is for doctors-to-doctors referral while different license might be doctor to nurse practitioner or physical therapist or other health care provider.</li> </ul>	
<b>Primary Responsibility</b>	<b>Former Version (April 29 draft)</b>	<b>Revised Version (July draft)</b>
Section 2	Section 2 included primary responsibility plus regulation of contracts, etc. A proposed section 2 was changed to the antikickback statute. (See below under Section 3)	Section 2. In addition to any specific policy referenced in chapters 3 and 4, 6 through 17, 20 through 28, and 34 through 36, it is the public policy adopted by the legislature that a health care provider's primary responsibility is the welfare of a patient or a client in all situations except those in which the primary responsibility is to public health.
Explanation of changes	There were requests for the primary responsibility statute to be reinserted into Title 37 for health care providers. No need to specify Title 37 because codification instructions place this section in Title 37.	
<b>Kickbacks prohibited</b>	<b>Former Version (April 29 draft)</b>	<b>Revised Version (July draft)</b>
Section 3	<p><b>SECTION 2. Primary responsibility -- contracts -- referrals -- definitions.</b> (1) A health care practitioner's primary responsibility is the welfare and well-being of the patient in all situations except those in which the primary responsibility is to public health.</p> <p>(2) (a) A health care practitioner may enter lawful contracts, agreements, and arrangements, including the acquisition of ownership interests in health care facilities, products, or equipment. (b) An employment contract, employment agreement, or contract-for-hire arrangement may not:</p> <p>(i) require referrals or an expected volume of referrals between parties; (ii) specify that referrals are a basis for remaining an investor or a party to the contract, agreement, or arrangement; (iii) base remuneration or scheduling decisions on an expected volume of referrals; or</p>	<p><b>SECTION 3. Kickbacks prohibited – limited exceptions.</b> (1) Except as provided in subsection (2), an employment contract, employment agreement, or contract-for-hire agreement with a health care provider, signed or renewed after [the effective date of this act], may not:</p> <p>(a) require exclusive referrals or an expected volume of referrals between parties; or (b) base remuneration or rebates on exclusive referrals or an expected volume of referrals. (2) Exceptions to the remuneration or rebate provisions of subsection (1)(b) include:</p> <p>(a) written contracts or agreements entered into after an open-bidding process; (b) community-based fair market value payments to a health care provider, including bonuses that do not relate to a specific volume or percentage of business based on referrals, to the extent allowed under the antikickback statute, 42 U.S.C. 1320a-7b by:</p> <p>(i) an employer, including a health care facility as defined in 50-5-101; or</p>

	<p>(iv) base bonuses on referrals or an expected volume of referrals.</p> <p>(3) For the purposes of [section 1] and this section, the following definitions apply:</p> <p>(a) A "health care practitioner" is a person licensed under Title 37, chapters 3 and 4, 6 through 17, 20 through 28, 34 through 36.</p> <p>(b) A "referral" is a written or oral order from a health care practitioner to a patient or client for health care services, including:</p> <p>(i) the forwarding of a patient to another health care practitioner or to a health care facility licensed under Title 50 or operated by a health care practitioner under Title 37 or to an entity that provides or supplies health services or health care supplies;</p> <p>(ii) a request or establishment of a plan of care that includes the provision of health services or health care supplies; and</p> <p>(iii) the information in [section 1(2)].</p>	<p>(ii) a group practice of two or more health care providers that has filed as a partnership, professional corporation, or limited liability company under Title 35 and that jointly:</p> <p>(A) uses office space, facilities, equipment, and personnel;</p> <p>(B) bills in the name of the group practice; and</p> <p>(C) treats receipts for services as receipts of the group practice;</p> <p>(c) amounts paid by a vendor to a purchasing agent for a health care provider or health care facility, defined under 50-5-101, under a written purchasing agreement or contract that specifies a fixed amount or a fixed percentage as provided in 42 U.S.C. 1320a-7b(b)(3)(C);</p> <p>(d) waivers, reductions, or amounts paid as provided under 42 U.S.C. 1320a-7b(b)(3)(D through H) and involving a federally qualified health care center, managed care organization, health maintenance organization, pharmacy, rural health clinic, a health care provider participating in a risk-sharing agreement, or other individual or entity covered by 42 U.S.C. 1320a-7b(b)(3)(D through H); and</p> <p>(e) written fair market value remuneration or compensation agreements involving health care facilities and health care providers that qualify for exceptions under 42 U.S.C. 1395nn(e)(1) through (8).</p>
<p><b>Explanation of changes</b></p> <p><i>See notes at end for more explanations of Stark Act summary.</i></p>	<ul style="list-style-type: none"> <li>• The antikickback statute would apply to all health care providers regardless of payment source.</li> <li>• The prohibition is against “exclusive” referrals or expected volume of referrals as well as basing remuneration or rebates on referrals, but there are exceptions.</li> <li>• Exceptions attempt to summarize the federal Stark and Antikickback laws, which have main themes like fair market value. A blanket reference to the Stark Act would be difficult to enforce because of the numerous exceptions. The attempt here is to repeat the key exceptions and provide key references to help with enforcement. The exceptions under 42 U.S.C. 1395nn(e)(1) through (8) relate to compensation arrangements: (1) is rental of office space and equipment; (2) is bona fide employment relationships (for identifiable services, consistent with fair market value and not determined into a manner that takes into account directly or indirectly the volume or value of any referrals by the referring physician); (3) is personal service arrangements (required to be in writing, for at least 1 year). Not sure what is meant by personal service arrangement; (4) physician incentive plan exception is for HMOs or entities that have compensation arrangements with physicians/physician groups that may have the effect of limiting services provided with respect to individuals enrolled with the entity; (5) is physician recruitment and is exempted if the physician is not required to refer patients to the hospital and remuneration is not determined in a manner that takes into account directly or indirectly the volume or value of referrals; (6) is isolated transaction as in one-time sale of practice or property with conditions; (7) is for certain group practice arrangements with a hospital for services provided by the group but billed by the hospital and began before Dec. 19, 1989, and is under a written agreement, with fixed in advance compensation at fair market value; and (8) is payments by a physician for items and services to a laboratory in exchange for clinical laboratory services or to an entity as payment at fair market value for items or services.</li> </ul>	
<b>Primary Responsibility</b>	<b>Former Version (April 29 draft)</b>	<b>Revised Version (July draft)</b>
Section 4	<b>SECTION 3. Primary responsibility.</b> The primary concern of any licensee under Title 50 must be the welfare of the patient except when public health takes precedence over the well-being of an individual.	<b>Section 4. Primary responsibility.</b> The primary concern of any licensee under this title must be the welfare of the patient except when public health takes precedence over the well-being of an individual.
<b>Explanation of changes</b>	No change except for Section number and use of term “this title” instead of specifying Title 50. Codification puts it in Title 50.	

<b>Enforcement, confidentiality, definitions</b>	<b>Former Version (April 29 draft)</b>	<b>Revised Version (July draft)</b>
Section 5	<p><b>Enforcement -- confidentiality -- definitions.</b> (1) (a) Upon receiving notification of a determination of unprofessional conduct by a Title 37 health care licensing board under 37-1-316(19) or Title 37 program under 37-1-410, the department shall investigate to determine if the unprofessional conduct was by a health care provider employed by a health care facility licensed under Title 50; and</p> <p>(b) If the relationship in subsection (1)(a) applies, the department shall determine whether the health care facility provided financial or scheduling benefits in violation of [section 2(2)(b)].</p> <p>(c) If the department determines that a health care facility contract or employment agreement or a consistent pattern of scheduling decisions violated [section 2(2)(b)] and had a causal relationship to the health care practitioner's violation of 37-1-316(19) or 37-1-410(1)(m), the department may take action as provided under 50-5-114.</p> <p>(2) The department may investigate an economic credentialing complaint unrelated to an unprofessional conduct finding as provided in subsection (1). As provided in [Title 5, chapter 5, part 1], the department may take action upon a finding that a health care facility has violated 50-5-117.</p> <p>(3) Until the department makes a determination as provided under subsection (1)(c), the department shall maintain the confidentiality of investigation records obtained from a health care licensing board and from its own investigation. The portions of an employment contract or agreement that violate state law do not have protection under privacy statutes.</p> <p>(4) For the purposes of this section, "health care provider" means an individual licensed, certified, or otherwise authorized under Title 37, except for an individual licensed under Title 37, chapter 18, to provide health care in the ordinary course of business or practice of a profession.</p>	<p><b>Section 5. Enforcement -- confidentiality -- definitions.</b> (1) (a) Upon receiving notification of a determination of unprofessional conduct by a Title 37 health care licensing board under 37-1-316(19) or Title 37 program under 37-1-410, the department shall investigate to determine if the health care provider subject to the unprofessional conduct determination had an employment contract, employment agreement, or contract-for-hire arrangement with a health care facility licensed under this title that violated [section 3].</p> <p>(b) If the department determines that the employment contract, employment agreement, or contract-for-hire arrangement violates [section 3], the provisions of parts 1 and 2 of this chapter apply.</p> <p>(2) Until the department makes a determination as provided under subsection (1)(b), the department shall maintain the confidentiality of investigation records obtained from a health care licensing board and from its own investigation. The portions of an employment contract or agreement that violate state law do not have protection under privacy statutes.</p> <p>(4) For the purposes of this section, "health care provider" means an individual licensed or certified under Title 37, chapters 3 and 4, 6 through 17, 20 through 28, and 34 through 36.</p>
Explanation of changes	<ul style="list-style-type: none"> <li>• The revised subsection (1) targets the employment contract, agreement, contract-for-hire arrangement specifically to determine if a violation of the antikickback section (section 3) occurred. It has been pointed out that a state investigation will trigger a federal investigation of what are now intended to be similar prohibitions. The revised subsection (1) does not include reference to financial or scheduling benefits as mentioned in the April 29 version (1)(c) but more clearly refers to what would be in a contract (1)(b), thus narrowing the investigation.</li> <li>• Subsection (1)(b) of the revised version directs DPHHS to use the civil penalties in parts 1 and 2 of chapter 5, Title 50, which allows a range of penalties from civil to criminal.</li> <li>• Subsection (2) of the old version is unnecessary if DPHHS' normal enforcement activities are reinstated in 50-5-117 by removing subsection (4).</li> <li>• Subsections (3) and (4) are basically the same in both versions. The revised version provides consistent references for health care providers.</li> </ul>	

37-1-135 Record Sharing	Former Version (April 29 draft)	Revised Version (July draft)
Section 6	<p>SECTION 5. "37-1-135. <b>Licensing investigation and review -- record access -- record sharing.</b> (1) Any person, firm, corporation, or association that performs background reviews, complaint investigations, or peer reviews pursuant to an agreement or contract with a state professional or occupational licensing board shall make available to the board and the legislative auditor, upon request, any and all records or other information gathered or compiled during the course of the background review, complaint investigation, or peer review.</p> <p>(2) Notwithstanding other confidentiality requirements, a board that determines that a licensee under chapters 3 and 4, 6 through 17, 20 through 28, and 34 through 36, has engaged in unprofessional conduct under 37-1-316(19) shall report its findings and provide any related investigation reports and records to the department of public health and human services for investigation as provided under [section 4]."</p>	<p>Section 6. <b>Licensing investigation and review -- record access -- record sharing.</b> (1) Any person, firm, corporation, or association that performs background reviews, complaint investigations, or peer reviews pursuant to an agreement or contract with a state professional or occupational licensing board shall make available to the board and the legislative auditor, upon request, any and all records or other information gathered or compiled during the course of the background review, complaint investigation, or peer review.</p> <p>(2) Notwithstanding other confidentiality requirements, a board or, for a program, the department shall report its findings that a licensee under chapters 3 and 4, 6 through 17, 20 through 28, and 34 through 36, has engaged in unprofessional conduct under 37-1-316(19) or 37-1-410(1)(m) and shall provide any related investigation reports and records to the department of public health and human services for investigation as provided under [section 5]."</p>
Explanation of changes	<ul style="list-style-type: none"> <li>• Adds in subsection (2) “or for a program, the department” because licensed addiction counselors, who would be covered by this bill, do not have a board and their enforcement is directly under the department.</li> <li>• Revised organization of paragraph to include new language above.</li> </ul>	
Title 37 Definitions	Former Version (April 29 draft)	Revised Version (July draft)
Section 7 (relevant change)	<p>(2) For the purposes of this part and 37-1-410, the term "conflict of interest" means a set of conditions in which a health care provider:</p> <p>— (a) exercises professional judgment concerning a patient's welfare that is unduly influenced directly or indirectly by a financial or investment interest;</p> <p>— (b) demonstrates an economically motivated referral pattern, as defined in 50-5-117;</p> <p>— (c) accepts, pays, or promises to pay a part of a fee in exchange for patient referrals;</p> <p>— (d) obtains any fee by fraud, deceit, or misrepresentation; or</p> <p>— (e) pays or receives, indirectly or directly, any fee, wage, commission, rebate, or other compensation for services not actually or personally rendered."</p>	<p>Section 7. (2) For the purposes of 37-1-410 and this part, the term "conflict of interest" refers to a recurring set of conditions in which a health care provider exercises professional judgment concerning a patient's welfare when making a referral that is unduly influenced directly or indirectly by an investment, employment, or contractual interest that is the beneficiary of a referral."</p>
Explanation of changes	<ul style="list-style-type: none"> <li>• New version adds “recurring” to set of conditions.</li> <li>• New version notes that the professional judgment is when making a referral</li> <li>• New version uses words “unduly influenced directly or indirectly by an investment, employment, or contractual interest that is the beneficiary of a referral.</li> <li>• Old version had words “economically motivated referral pattern”, which was used in the economic credentialing statute but has been removed.</li> </ul>	

	<ul style="list-style-type: none"> <li>• Old version had kickback references, which are illegal under the Antikickback Statute and thus not needed.</li> <li>• Old version referenced fraud, which also is already illegal.</li> <li>• Old version included the pays or receives commission, rebate, etc. for services not personally rendered, etc. This runs afoul of all the exceptions that are now in the Antikickback Statute and in Stark regarding definitions of compensation. It would be difficult to enforce.</li> </ul>	
<b>Unprofessional conduct 37-1-316</b>	<b>Former Version (April 29 draft)</b>	<b>Revised Version (July draft)</b>
Section 8 (relevant change)	<u>(19) for health care practitioners licensed under Title 37, chapters 3 and 4, 6 through 17, 20 through 28, and 34 through 36 a finding of conflict of interest detrimental to a patient's welfare and safety."</u>	<u>(19) for health care practitioners licensed under Title 37, chapters 3 and 4, 6 through 17, 20 through 28, and 34 through 36 a determination of a conflict of interest or violation of [section 3]."</u>
Explanation of changes	<ul style="list-style-type: none"> <li>• New version uses definition of conflict of interest by itself or a violation of Section 3, the antikickback statute.</li> <li>• Old version references "detrimental to a patient's welfare and safety". Might be difficult to prove. Also, as stated during comment period, a kickback might be beneficial to a patient's welfare and safety. So then what?</li> </ul>	
<b>Unprofessional conduct 37-1-410</b>	<b>Former Version (April 29 draft)</b>	<b>Revised Version (July draft)</b>
Section 9 (relevant change)	<u>(m) engaging in a conflict of interest, as defined in 37-1-302, detrimental to a patient's welfare and safety.</u>	<u>(m) engaging in a conflict of interest, as defined in 37-1-302, or a violation of [section 3].</u>
Explanation of changes	<ul style="list-style-type: none"> <li>• New version uses definition of conflict of interest by itself or a violation of Section 3, the antikickback statute.</li> <li>• Old version references detrimental to a patient's welfare and safety. Might be difficult to prove. Also, as stated during comment period, a kickback might be beneficial to a patient's welfare and safety.</li> </ul>	
<b>Discrimination prohibited</b>	<b>Former Version (April 29 draft)</b>	<b>Revised Version (July draft)</b>
Section 10 (relevant change)	<del>(4) Except for a hospital that employs its medical staff, a hospital considering an application for staff membership or granting privileges within the scope of the applicant's license may not deny the application or privileges because the applicant is licensed under Title 37, chapter 6</del> <del>(5) This section does not preclude a hospital from limiting membership or privileges based on education, training, or other relevant criteria."</del>	(4) Except for a hospital that employs its medical staff, a hospital considering an application for staff membership or granting privileges within the scope of the applicant's license may not deny the application or privileges because the applicant is licensed under Title 37, chapter 6.
Explanation of changes	<ul style="list-style-type: none"> <li>• Main reason this section (50-5-105) is included is because it had the sunset section attached. One purpose of the bill is to remove the sunset language.</li> <li>• Old version also had deleted a portion of the statute that referred to podiatrists as an attempt at code cleanup. This is not necessary nor was it requested or commented upon, so the revised version puts subsection (4) back in.</li> </ul>	
<b>Economic credentialing</b>	<b>Former Version (April 29 draft)</b>	<b>Revised Version (July draft)</b>
Section 11 Sub (1)	<b>50-5-117. (Temporary) Economic credentialing of physicians prohibited -- definitions.</b> (1) A hospital may not engage in economic credentialing by: (a) except as may be required for medicare certification or	<b>Economic credentialing of physicians prohibited -- definitions.</b> (1) <u>Except to the extent necessary to determine physician competency or to comply with medicare or medicaid certification under Titles XVIII and XIX of the Social Security Act, respectively, or for accreditation by the joint</u>

	<p>for accreditation by the joint commission on accreditation of healthcare organizations, requiring a physician requesting medical staff membership or medical staff privileges to agree to make referrals to that hospital or to any facility related to the hospital;</p> <p>(b) refusing to grant staff membership or medical staff privileges or conditioning or otherwise limiting a physician's medical staff participation because the physician or a partner, associate, or employee of the physician:</p> <p>(i) provides medical or health care services at, has an ownership interest in, or occupies a leadership position on the medical staff of a different hospital, hospital system, or health care facility; or</p> <p>(ii) participates or does not participate in any particular health plan; or</p> <p>(c) refusing to grant participatory status in a hospital or hospital system health plan to a physician or a partner, associate, or employee of the physician because the physician or partner, associate, or employee of the physician provides medical or health care services at, has an ownership interest in, or occupies a leadership position on the medical staff of a different hospital, hospital system, or health care facility.</p>	<p><u>commission on accreditation of healthcare organizations or the accreditation association for ambulatory health care, a hospital or outpatient center for surgical services</u> may not engage in economic credentialing by:</p> <p>(a) <del>except as may be required for medicare certification or for accreditation by the joint commission on accreditation of healthcare organizations,</del> requiring a physician requesting medical staff membership or medical staff privileges to agree to make referrals to that hospital, <u>outpatient center for surgical services</u>, or to any facility related to the hospital or <u>outpatient center for surgical services</u>;</p> <p>(b) refusing to grant staff membership or medical staff privileges or conditioning or otherwise limiting a physician's medical staff participation because the physician or a partner, associate, or employee of the physician:</p> <p>(i) provides medical or health care services at, has an ownership interest in, or occupies a leadership position on the medical staff of a different hospital, hospital system, or health care facility; or</p> <p>(ii) participates or does not participate in any particular health plan; or</p> <p>(c) refusing to grant participatory status in a hospital or hospital system health plan <u>or outpatient center for surgical services health plan</u> to a physician <del>or a partner, associate, or employee of the physician who has medical staff privileges</del> because the physician or partner, associate, or employee of the physician provides medical or health care services at, has an ownership interest in, or occupies a leadership position on the medical staff of a different hospital, hospital system, or health care facility.</p>
<p>Explanation of changes sub (1)</p>	<ul style="list-style-type: none"> <li>• Old version of Subsection (1) is existing law.</li> <li>• The Montana Hospital Association (MHA) suggested a revised introduction (1) to make all the types of conditions subject to certification requirements. Listed in the new version are certification requirements for Medicare or Medicaid and for accreditation by either JCAHO or the association that accredits ambulatory surgery centers. MHA had requested “as required by any federal or state laws” but drafters are asked to be specific when citing other laws (there are exceptions).</li> <li>• The new version includes a prohibition on economic credentialing by ambulatory surgery centers otherwise known as outpatient centers for surgical services (which is the defined version in Title 50).</li> <li>• Subsection (1)(c) removes the partners, associates, or employees of the physician from participatory status in a hospital or hospital system health plan or outpatient center for surgical services health plan. The MHA had requested that all of this section be removed because a hospital does not grant participation in a system health plan. The subcommittee suggested it remain but narrowed its application. It is unclear whether the original reason for inclusion was to keep physicians out of a hospital if they did not qualify for a hospital system health plan (thus allowing health plans to do the economic credentialing) or if the subsection was an attempt by physicians to get health care coverage for their assistants, etc. By adding the words “who has medical staff privileges”, the approach is that the physician who qualifies for medical staff privileges then can qualify for participatory status in a health plan, but the wording does not condition the medical staff privileges on participatory status in a health plan.</li> </ul>	
	<p>(2) Notwithstanding the prohibitions in subsection (1), a hospital may:</p> <p><del>_____ (a) refuse to appoint a physician to the governing body of the hospital or to the position of president of the medical staff or presiding officer of a medical staff committee if a conflict of interest exists or the physician or a partner or employee of the physician provides medical or health care services at, has an ownership</del></p>	<p>(2) Notwithstanding the prohibitions in subsection (1), a hospital <u>or outpatient center for surgical services</u> may:</p> <p><del>_____ (a) refuse to appoint a physician to the governing body of the hospital</del> <u>board</u> or to the position of president of the medical staff or presiding officer of a medical staff committee if <u>a conflict of interest exists</u> or the physician or a partner or employee of the physician provides medical or health care services at, <del>has an ownership interest in,</del> or occupies a leadership position on the</p>



	<p><del>interest in</del>, or occupies a leadership position on the medical staff of a different hospital, hospital system, or health care facility; or</p> <p><del>(b) exclude a physician member of the board, the president of the hospital medical staff, or presiding officer of a medical staff committee from hospital-related decisions and information if the physician member of the board, president of the hospital staff, or presiding officer of a medical staff committee has a conflict of interest relevant to those decisions or that information.</del></p>	<p>medical staff of a different hospital, hospital system, or health care facility; or</p> <p><u>(b) require recusal of a physician member of the board, the president of the medical staff of the hospital or outpatient center for surgical services, or presiding officer of a medical staff committee from financial decisions and information related to the hospital or outpatient center for surgical services if the physician member of the board, president of the hospital medical staff or outpatient center for surgical services staff, or presiding officer of a medical staff committee has a conflict of interest relevant to those decisions or that information.</u></p>
<p>Explanation of changes sub (2)</p>	<ul style="list-style-type: none"> <li>• Old version would have prevented hospitals from appointing a physician to the position of president of the medical staff or the presiding officer of a medical staff committee if that physician had a conflict or interest or occupied a leadership position on a medical staff elsewhere.</li> <li>• New version substitutes board for governing body (and later defines it), and allows hospital to refuse to appoint to president of the medical staff, etc., which is more in line with current law. Adds the words “if a conflict of interest exists” and later defines conflict of interest.</li> <li>• Old version attempted to specify when a hospital could exclude a physician from hospital-related decisions and information.</li> <li>• New version specifies that a hospital may require recusal from financial decisions and information if there is a conflict of interest relevant to those decisions or that information.</li> </ul>	
	<p>(3) For the purposes of this section, the following definitions apply:</p> <p>(a) <u>"Economically motivated referral pattern" means a referral pattern that demonstrates consistent referrals based on a patient's health insurance coverage or ability to pay;</u></p> <p><u>(b) (i) "Conflict of interest" means a situation in which a physician or an immediate family member as defined in 15-30-602, partner, or employee of the physician has a financial interest in any licensed health care facility that may compete directly with a hospital licensed under this title, chapter 5.</u></p> <p><u>(ii) For the purposes of subsection (3)(b)(i), a financial interest exists if a person directly or indirectly holds through business or investment an ownership interest in any licensed health care facility that competes with a hospital licensed under this title, chapter 5.</u></p> <p><u>(c) (i) "Economic credentialing" means the denial of a physician's application for staff membership or clinical privileges to practice medicine in a hospital on criteria other than the individual's education, training, current competence, experience, ability, personal character, and judgment.</u></p> <p><u>(ii) This term does not mean use by the hospital of:</u></p> <p><u>(A) exclusive contracts with physicians, if the contracts do not violate the unfair trade practices act under Title 30, chapter 14, part 2;</u></p> <p><u>(B) equitable medical staff on-call requirements;</u></p> <p><u>(C) disciplinary actions upon a finding by the board of medical examiners, provided for 2-15-1731, that a physician or a physician group has engaged in economically motivated referral patterns;</u></p> <p><u>(D) adherence to a formulary approved by the medical staff;</u></p>	<p>(3) For the purposes of this section, the following definitions apply:</p> <p>(a) <u>"Board" means the governing body or board of directors of a hospital or outpatient center for surgical services.</u></p> <p><u>(b) (i) "Conflict of interest" means, notwithstanding the board's own conflict of interest policy, a situation in which a physician in a leadership position either individually or through an immediate family member as defined in 15-30-602, partner, or employee of the physician has a financial interest in any licensed health care facility that may compromise the board's fiduciary responsibility.</u></p> <p><u>(ii) For the purposes of subsection (3)(b)(i), a financial interest exists if a person directly or indirectly holds through business or investment a greater than 5% ownership interest in any health care facility licensed under chapter 5, that offers similar services as a hospital licensed under chapter 5.</u></p> <p><u>(c) (i) "Economic credentialing" means the denial of a physician's application for staff membership or clinical privileges to practice medicine in a hospital on criteria other than the individual's education, training, current competence, experience, ability, personal character, and judgment.</u></p> <p><u>(ii) This term does not mean use by the hospital or outpatient center for surgical services of:</u></p> <p><u>(A) exclusive contracts with physicians, if the contracts do not violate the unfair trade practices act under Title 30, chapter 14, part 2;</u></p> <p><u>(B) equitable medical staff on-call requirements; as determined by a super majority of the medical staff of the hospital or outpatient center for surgical services. The on-call requirements may not violate 30-14-103.</u></p> <p><u>(C) adherence to a formulary approved by the medical staff; or</u></p> <p><u>(D) other medical staff policy adopted to manage health care costs or improve quality.</u></p>

	<p>or</p> <p><del>(iv)</del>(E) other medical staff policy adopted to manage health care costs or improve quality OR other policies that apply to <u>medical staff and were adopted with concurrence of medical staff to manage health care costs or improve quality.</u></p> <p><del>(b)</del>(d) "Health care facility" has the meaning provided in 50-5-101 <del>and includes diagnostic facilities.</del></p> <p><del>(e)</del>(e) "Health plan" means a plan offered by any person, employer, trust, government agency, association, corporation, or other entity to provide, sponsor, arrange for, indemnify another for, or pay for health care services to eligible members, insureds, enrollees, employees, participants, beneficiaries, or dependents, including but not limited to a health plan provided by an insurance company, health service organization, health maintenance organization, preferred provider organization, self-insured health plan, captive insurer, multiple employee welfare arrangement, workers' compensation plan, medicare, or medicaid.</p> <p><del>(d)</del>(f) "Physician" has the meaning provided in 37-3-102.</p>	<p><del>(b)</del>(d) "Health care facility" has the meaning provided in 50-5-101 <del>and includes diagnostic facilities.</del></p> <p><del>(e)</del>(e) "Health plan" means a plan offered by any person, employer, trust, government agency, association, corporation, or other entity to provide, sponsor, arrange for, indemnify another for, or pay for health care services to eligible members, insureds, enrollees, employees, participants, beneficiaries, or dependents, including but not limited to a health plan provided by an insurance company, health service organization, health maintenance organization, preferred provider organization, self-insured health plan, captive insurer, multiple employee welfare arrangement, workers' compensation plan, medicare, or medicaid.</p> <p><del>(d)</del>(f) "Physician" has the meaning provided in 37-3-102.</p>
Explanation of changes sub (3)	<ul style="list-style-type: none"> <li>• New version adds definition of board, removes “economically motivated referral pattern”.</li> <li>• New version conflict of interest definition recognizes that a board may have a separate conflict of interest policy that applies to all its members and further states that a conflict of interest exists if a physician in a leadership position either individually or through an immediate family member, partner, or employee has a financial interest in a health care facility that may compromise the board’s fiduciary responsibility. By referencing health care facility, which is defined as a Montana entity, there is no current concern about financial interests in facilities traded under the Securities Exchange Commission, which is used by some states to exempt some types of financial interests. But the definition of health care facility also does not include diagnostic facilities that might be owned by a physician or physician group.</li> <li>• Subsection (3)(b)(ii) in new version defines financial interest as more than 5% ownership in any health care facility licensed under Title 50, chapter 5, that offers similar services as a hospital licensed under chapter 5 of Title 50.</li> <li>• Old version definition of financial interest did not have any trigger and used the word “compete” instead of “offers similar services”.</li> <li>• Both versions retain word “equitable” before medical staff on-call arrangements. New version includes requirement for super majority, which may by rule be 2/3 or 3/4 and further cannot violate the unfair trade practices statute outlawing unfair methods of competition.</li> <li>• New version omits disciplinary actions determined by the Board of Medical Examiners, which is in old version and uses term “economically motivated referral pattern”.</li> <li>• New version omits reference to other policies that apply to medical staff and that were adopted by concurrence of medical staff. This was optional language to existing reference to medical staff policies adopted to manage costs.</li> </ul>	
	(4) For the purposes of this section, the provisions of 50-5-207 do not apply. <del>(Terminates June 30, 2009 sec. 6, Ch. 351, L. 2007.)</del> "	<del>(4) For the purposes of this section, the provisions of 50-5-207 do not apply. (Terminates June 30, 2009 sec. 6, Ch. 351, L. 2007.)</del> "
Explanation of changes sub (4)	<ul style="list-style-type: none"> <li>• Old version is existing language.</li> <li>• New version would reinstate the DPHHS enforcement provisions in 50-5-207.</li> </ul>	
Enforcement provisions of 50-5-207	<b>Former Version (April 29 draft)</b>	<b>Revised Version (July draft)</b>

Section 12 (relevant change)	(2) The department may reduce a license to provisional status if: <u>(a) as a result of an inspection it is determined that the facility has failed to comply with a provision of part 1 or 2 of this chapter or has failed to comply with a rule, license provision, or order adopted or issued pursuant to part 1 or 2; or</u> <u>(b) the department has determined through an investigation under [section 4] that a health care facility contributed to a determination of unprofessional conduct under 37-1-316(19) or 37-1-410(1)(m) affecting a health care provider's license.</u>	(2) The department may reduce a license to provisional status if as a result of an inspection it is determined that the facility has failed to comply with a provision of part 1 or 2 of this chapter or has failed to comply with a rule, license provision, or order adopted or issued pursuant to part 1 or 2.
Explanation of changes	<ul style="list-style-type: none"> <li>• Old version provided enforcement through provisional license approach.</li> <li>• New version removes reference to enforcement of unprofessional conduct through provisional license. Revised section 5 gives full range of enforcement options under chapter 5, parts 1 and 2.</li> </ul>	
Section 13	Same in both versions – repeals sunset.	
Section 14	Codifies sections. Old version had 2 new sections in Title 37 and 2 new sections in Title 50. New version has 3 new sections in Title 37 and 2 new sections in Title 50.	
Section 15	Effective date – Immediate effective date same in both versions.	

**Additional Notes on Stark Act summary as reflected in Section 3 :**

<p><b>SECTION 3. Kickbacks prohibited – limited exceptions.</b> (1) Except as provided in subsection (2), an employment contract, employment agreement, or contract-for-hire agreement with a health care provider, signed or renewed after [the effective date of this act], may not:</p> <p>(a) require exclusive referrals or an expected volume of referrals between parties; or</p> <p>(b) base remuneration or rebates on exclusive referrals or an expected volume of referrals.</p>
<p><b>Federal Register V. 69 #59, March 26, 2004: p. 16087:</b></p> <p>“A commenter expressed concern that physicians employed by health care systems are pressured into referring to DHS [designated health services] entities within the same health system, sometimes without regard to a patient’s best interests. Other commenters, however, urged that employers should be allowed to control their employees and should be able to require referrals to the employer or an entity affiliated with the employer. These commenters believed that the proper focus is on whether the referral requirement interferes with a physician’s medical judgment. ...”</p> <p>RESPONSE: “...we believe that section 1877 of the Act was not intended to interfere unduly with legitimate employment and health system structures. As discussed above, we have narrowed the rule for directed referrals in §411.354(d)(4) to employers, managed care organizations, and certain contractual arrangements (including many emergency room physician contracts). We have concluded that a referral restriction will not violate the volume and value of referrals standard in section 1877 of the Act <b>if</b> –</p> <ul style="list-style-type: none"> <li>• The referring physician is compensated at <b>fair market value</b> for services performed in an arrangement that otherwise fits within the employment (or another) exception;</li> <li>• The referral restriction relates solely to the physician’s services covered by the scope of the employment or contract and is reasonably necessary to effectuate the legitimate purposes of the compensation relationship; and</li> <li>• <b>Referrals are not required</b> (directly or indirectly) –”</li> </ul> <p>“... personally performed DHS are not referrals within the meaning of section 1877 of the Act. Accordingly, physicians may be paid productivity bonuses based on personally performed services. ... In addition, nothing in the exception precludes a productivity bonus based solely on personally performed supervision of services that are not DHS, since the bonus would not take into account the volume or value of DHS referrals. Productivity bonuses based on supervising DHS raise a different issue. We are concerned that, in some cases, a payment for supervision services may merely be a proxy payment for having generated the DHS being supervised. In many cases, especially in hospitals, the supervision required under Medicare rules is minimal, .... Accordingly, we are concerned that such payments could mask improper cross-referral</p>

or circumventing schemes. We note that any payment for supervision services must meet the **fair market value** standard in the exception. As for productivity bonuses for employees of group practices, we expect that most group practices will rely on the in-office ancillary services exception, rather than the employment exception, to protect referrals by employed physicians....” [NOTE: the definition of referral now says “outside of a routine office exam” – rather than “in-office ancillary services”. This might be necessary to change, for consistency with federal law.]

(2) Exceptions to the remuneration or rebate provisions of subsection (1)(b) include:

(a) written contracts or agreements entered into after an open-bidding process if the discounts or reductions in price are properly disclosed after the contract is awarded, as provided by rule;

(b) fair market value payments to a health care provider, including bonuses that do not relate to a specific volume or percentage of business based on referrals, to the extent allowed under the antikickback statute, 42 U.S.C. 1320a-7b by:

- (i) an employer, including a health care facility as defined in 50-5-101; or
- (ii) a group practice of two or more health care providers that has filed as a partnership, professional corporation, or limited liability company under Title 35 and that jointly:
  - (A) uses office space, facilities, equipment, and personnel;
  - (B) bills in the name of the group practice; and
  - (C) treats receipts for services as receipts of the group practice;

(c) amounts paid by a vendor to a purchasing agent for a health care provider or health care facility, defined under 50-5-101, under a written purchasing agreement or contract that specifies a fixed amount or a fixed percentage as provided in 42 U.S.C. 1320a-7b(b)(3)(C);

(d) waivers, reductions, or amounts paid as provided under 42 U.S.C. 1320a-7b(b)(3)(D through H) and involving a federally qualified health care center, managed care organization, health maintenance organization, pharmacy, rural health clinic, a health care provider participating in a risk-sharing agreement, or other individual or entity covered by 42 U.S.C. 1320a-7b(b)(3)(D through H); and

(e) written fair market value remuneration or compensation agreements involving health care facilities and health care providers that qualify for exceptions under 42 U.S.C. 1395nn(e)(1) through (8).

This is discussed in Explanation on page 4.