2019 HOUSE HUMAN SERVICES COMMITTEE

HB 1373

2019 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Union Room, State Capitol

HB 1373
1/22/2019
31205

☐ Subcommittee
☐ Conference Committee

Elaine Stromme by Risa Bergquist

Explanation or reason for introduction of bill/resolution:

Relating to state medical anti-kickback laws; to provide a penalty; and to provide an effective date.

Minutes: Attachment 1-2

Chairman Weisz: Call the meeting to order.

Representative Marvin Nelson: HB 1373 is aimed at helping the controlled medical cost by prohibiting the practice of providing a medical doctor for referrals Administrators that want health providers to use their facilities and the other personal they have is what this bill is aimed at. **(see attachment 1page 2)** Anti-kickback Statue. They prohibit kickback; generally, Medicare and Medicaid but they don't prohibit private pay. The federal law states that if we are totally different practices then they apply, if we're under the same practice they do not apply. Hospital administrator was on the radio talking about how he paid his doctors for referrals and for running more tests. The extra tests put you in risk not just financially but physically. Overall health care cost is going up because of the number of procedures not the procedures themselves. The health council is in charge of making rules and the rules will state when they're more restricted in federal laws. The other part of the bill exempts patients; we're not talking about free samples from their doctors. Thousand dollars of 110% of the financial benefit given to the provider. If these type of cases didn't happen then no one would be opposed to this bill.

Chairmen Weisz: Questions by the committee

6:35 Representative Porter: Page 3 of the bill you are talking about the fines, where is that money to go? Where do you want it to go?

Representative Nelson: I'd like to see the money to go in the funds where we take care of the health of individuals, it could go general fund.

Representative Porter: Health Department is going to be in charge of this but we don't see a fiscal note or an impact, they certainly can't do this without employees. Someone has to investigate the claim.

Representative Westlind: What do you think the frequency of this is? Is it just in the major companies?

Representative Nelson: I believe it's pretty common, when you get into the large integrated units**,** there's a lot of opportunity there. They also can refuse to refer you outside of their network. Once you're in their system they will keep you there. They are actually telling the doctors they need to refer more patients and order more tests.

12:35 Chairman Weisz: The additional ordering of extra tests really can't be addressed by this right?

Representative Nelson: No I really didn't want to go there.

13:20 Kathrin Volochenko Nonpartisan League: As a former patient of small rural clinic I personally have been a victim of referrals. I just simply want to testify in support based on that, now understanding more about what goes on behind the scenes I better understand and support this.

15:15-20:20 Melissa Hauer, General Counsel of the North Dakota Hospital Association: (see attachment 2)

Chairman Weisz: Questions?

Representative Porter: Inside of Representative Nelson's testimony he mentioned a particular practitioner that was inside of health care system that was told to do more inside the system. You're saying if he had reported that as a whistle blower that practice would already be considered illegal?

Ms. Hauer: The example that would be clearly illegal would be if a provider said I will pay another referral source $1500 dollars for every cancer patient, that would be illegal. It's not illegal for employer of a health care professional to say we need to look at your production. To pay that provider depending on the tests or patents seen, that would be illegal.

Representative Porter: His example was that you're not referring enough patients internally to our other specialist, would that be illegal?

Ms. Hauer: You can't pay a physician per procedure, per test ordered, per patient seen; you can pay a provider based on production. You have to make sure you are paying within fair market value and there are charts that hospitals have to use that break it down by specialty and by region as to what you can pay a specialist in a certain area.

Representative Porter: I'm focusing in on the primary care physician, can their salary or employment be based on the number of referrals to the rest of the specialists inside of their system?

Ms. Hauer: If I were the attorney advising that hospital I would say no; you should not be doing that, or requiring a certain number of referrals.

Chairman Weisz: It seems like they are kind of over lapping here, I understand what you are saying per procedure but production is the number of patients you would see.

Ms. Hauer: There's a thing that CMS does, it's called a Work Relative Value Unit, and what they take into account is the cost of providing something to a patient. How much physician time is it going to take? How much skill does it take? Are you a surgeon vs. primary care doctor? I surgeon would have a higher RBU then a primary care doctor. That is how production is caged.

Representative Ruby: If this were to pass what would be the change?

Ms. Hauer: We don't know because we don't know what the State Health Council would adopt as rules, we don't know how it would be more restrictive.

Chairman Weisz:Further questions? Further Opposition?

26:35 Courtney Koebele, North Dakota Medical Association: We also opposed this bill.

Representative Porter: We need to hear about the fiscal note.

27:35 Dirk Wilke, Chief Operating Officer for the North Dakota Department of Health: We didn't get a fiscal note sent to us, we are still analyzing what it would mean in terms of work load. We are checking with other states that do do this. Currently we are neutral on this.

Representative Porter: So Minnesota does this, is it because there is loop holes between the federal and system?

Mr. Wilke: We are hoping to get more information on this this week.

Chairman Weisz: Anything further? We will close this meeting.

2019 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Union Room, State Capitol

HB 1373
2/5/2019
32180

☐ Subcommittee
☐ Conference Committee

Committee Clerk Signature: Nicole Klaman by Donna Whetham

Explanation or reason for introduction of bill/resolution:
Relating to state medical anti-kickback: to provide a penalty; to provide an effective date.

Minutes:

Chairman Weisz: Opened hearing on HB 1373.

Rep. Porter: I would move a Do Not Pass on HB 1373. The bill creates a duplicate of what is already in federal law, no need to duplicate things.

Vice Chairman Rohr: Seconded.

Chairman Weisz: Any discussion?

Rep. Porter: The bill itself creates something that is duplicative of what is in law already. As I looked through the law and federal law and the scenarios brought forth there wasn't really anything that wasn't covered by federal law. You cannot tell somebody in their practice that they have to order more labs. You can tell them they have to be more productive and have their relative value unit at a certain level for their payment. The inside referrals and procedures and the tests is already covered under federal law. I don't see a need to duplicate that.

Representative Schneider: I think we have literally hundreds of examples where we duplicate federal law into our state statutes. Part of that is due to the ability to enforce it at the state level. I think the goal was to be an anticorruption provision and have the state health officer access a fine against the person who violates the section. I would not move a do pass but I resist a Do Not Pass on this.

Chairman Weisz: Any further discussion on a Do Not Pass on HB 1373? Seeing none.

Roll call vote taken: Yes 10 No 2 Absent 2. Motion carries on a Do Not Pass on HB 1373.

Vice Chairman Rohr: Will carry the bill.

Date: 2-5-2019
Roll Call Vote #: 1

2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. HB 1373

House Human Services Committee

☐ Subcommittee

Amendment LC# or Description: _____

Recommendation: ☐ Adopt Amendment
☐ Do Pass ☒ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Rep. Porter Seconded By Vice Chairman Rohr

Representatives	Yes	No	Representatives	Yes	No
Robin Weisz - Chairman	X		Gretchen Dobervich		X
Karen M. Rohr – Vice Chairman	X		Mary Schneider		X
Dick Anderson	X				
Chuck Damschen	X				
Bill Devlin	X				
Clayton Fegley	X				
Dwight Kiefert	A				
Todd Porter	X				
Matthew Ruby	X				
Bill Tveit	A				
Greg Westlind	X				
Kathy Skroch	X				

Total (Yes) 10 No 2

Absent 2

Floor Assignment Vice Chairman Rohr

If the vote is on an amendment, briefly indicate intent:

Motion carries for a Do Not Pass.

REPORT OF STANDING COMMITTEE

HB 1373: Human Services Committee (Rep. Weisz, Chairman) recommends **DO NOT PASS** (10 YEAS, 2 NAYS, 2 ABSENT AND NOT VOTING). HB 1373 was placed on the Eleventh order on the calendar.

2019 TESTIMONY

HB 1373

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A Roadmap for New Physicians
Fraud & Abuse Laws

I. Physician Relationships with Payers Introduction

The five most important Federal fraud and abuse laws that apply to physicians are the False Claims Act (FCA), the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (Stark law), the Exclusion Authorities, and the Civil Monetary Penalties Law (CMPL). Government agencies, including the Department of Justice, the Department of Health & Human Services Office of Inspector General (OIG), and the Centers for Medicare & Medicaid Services (CMS), are charged with enforcing these laws. As you begin your career, it is crucial to understand these laws not only because following them is the right thing to do, but also because violating them could result in criminal penalties, civil fines, exclusion from the Federal health care programs, or loss of your medical license from your State medical board.

False Claims Act [31 U.S.C. § § 3729-3733]

The civil FCA protects the Government from being overcharged or sold shoddy goods or services. It is illegal to submit claims for payment to Medicare or Medicaid that you know or should know are false or fraudulent. Filing false claims may result in fines of up to three times the programs' loss plus $11,000 per claim filed. Under the civil FCA, each instance of an item or a service billed to Medicare or Medicaid counts as a claim, so fines can add up quickly. The fact that a claim results from a kickback or is made in violation of the Stark law also may render it false or fraudulent, creating liability under the civil FCA as well as the AKS or Stark law.

Under the civil FCA, no specific intent to defraud is required. The civil FCA defines "knowing" to include not only actual knowledge but also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. Further, the civil FCA contains a whistleblower provision that allows a

private individual to file a lawsuit on behalf of the United States and entitles that whistleblower to a percentage of any recoveries. Whistleblowers could be current or ex-business partners, hospital or office staff, patients, or competitors.

There also is a criminal FCA (18 U.S.C. § 287). Criminal penalties for submitting false claims include imprisonment and criminal fines. Physicians have gone to prison for submitting false health care claims. OIG also may impose administrative civil monetary penalties for false or fraudulent claims, as discussed below.

Anti-Kickback Statute [42 U.S.C. § 1320a-7b(b)]

The AKS is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients). Remuneration includes anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies. In some industries, it is acceptable to reward those who refer business to you. However, in the Federal health care programs, paying for referrals is a crime. The statute covers the payers of kickbacks-those who offer or pay remuneration- as well as the recipients of kickbacks-those who solicit or receive remuneration. Each party's intent is a key element of their liability under the AKS.

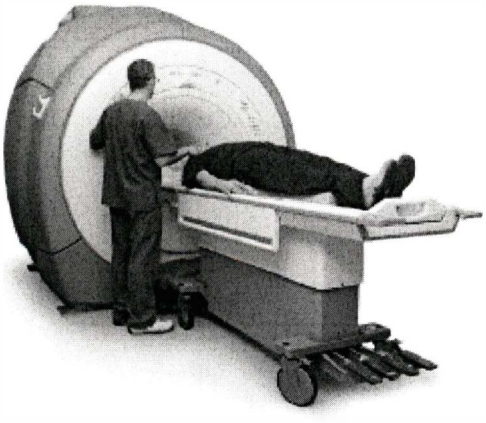
Criminal penalties and administrative sanctions for violating the AKS include fines, jail terms, and exclusion from participation in the Federal health care programs. Under the CMPL, physicians who pay or accept kickbacks also face penalties of up to $50,000 per kickback plus three times the amount of the remuneration.

Safe harbors protect certain payment and business practices that could otherwise implicate the AKS from criminal and civil prosecution. To be protected by a safe harbor, an arrangement must fit squarely in the safe harbor and satisfy all of its requirements. Some safe harbors address personal services and rental agreements, investments in ambulatory surgical centers, and payments to bona fide employees.

For additional information on safe harbors, see "OIG's Safe Harbor Regulations."

As a physician, you are an attractive target for kickback schemes because you can be a source of referrals for fellow physicians or other health care providers and suppliers. You decide what drugs your patients use, which specialists they see, and what health care services and supplies they receive.

Many people and companies want your patients' business and would pay you to send that business their way. Just as it is illegal for you to take money from providers and suppliers in return for the referral of your Medicare and Medicaid patients, it is illegal for you to pay others to refer their Medicare and Medicaid patients to you.



Kickbacks in health care can lead to:

- Overutilization
- Increased program costs
- Corruption of medical decisionmaking
- Patient steering
- Unfair competition

The kickback prohibition applies to all sources of referrals, even patients. For example, where the Medicare and Medicaid programs require patients to pay copays for services, you are generally required to collect that money from your patients. Routinely waiving these copays could implicate the AKS and you may not advertise that you will forgive copayments. However, you are free to waive a copayment if you make an individual determination that the patient cannot afford to pay or if your reasonable collection efforts fail. It is also legal to provide free or discounted services to uninsured people.

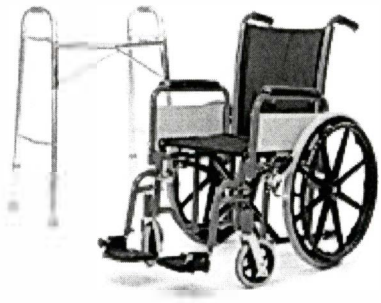
Besides the AKS, the beneficiary inducement statute (42 U.S.C. § 1320a-7a(a)(5)) also imposes civil monetary penalties on physicians who offer remuneration to Medicare and Medicaid beneficiaries to influence them to use their services.

The Government does not need to prove patient harm or financial loss to the programs to show that a physician violated the AKS. A physician can be guilty of violating the AKS even if the physician actually rendered the service and the service was medically necessary. Taking money or gifts from a drug or device company or a durable medical equipment (DME) supplier is not justified by the argument that you would have

prescribed that drug or ordered that wheelchair even without a kickback.

Physician Self-Referral Law [42 U.S.C. § 1395nn]

The Physician Self-Referral Law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership/investment interests and compensation arrangements. For example, if you invest in an imaging center, the Stark law requires the resulting financial relationship to fit within an exception or you may not refer patients to the facility and the entity may not bill for the referred imaging services.



"Designated health services" are:

- clinical laboratory services;
- physical therapy, occupational therapy, and outpatient speech-language pathology services;
- radiology and certain other imaging services;
- radiation therapy services and supplies;
- DME and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services.

For more information, see CMS's Stark law Web site.

The Stark law is a strict liability statute, which means proof of specific intent to violate the law is not required. The Stark law prohibits the submission, or causing the submission, of claims in violation of the law's restrictions on referrals. Penalties for

physicians who violate the Stark law include fines as well as exclusion from participation in the Federal health care programs.

Exclusion Statute [42 U.S.C. § 1320a-7]

OIG is legally required to exclude from participation in all Federal health care programs individuals and entities convicted of the following types of criminal offenses: (1) Medicare or Medicaid fraud, as well as any other offenses related to the delivery of items or services under Medicare or Medicaid; (2) patient abuse or neglect; (3) felony convictions for other health-care-related fraud, theft, or other financial misconduct; and (4) felony convictions for unlawful manufacture, distribution, prescription, or dispensing of controlled substances. OIG has discretion to exclude individuals and entities on several other grounds, including misdemeanor convictions related to health care fraud other than Medicare or Medicaid fraud or misdemeanor convictions in connection with the unlawful manufacture, distribution, prescription, or dispensing of controlled substances; suspension, revocation, or surrender of a license to provide health care for reasons bearing on professional competence, professional performance, or financial integrity; provision of unnecessary or substandard services; submission of false or fraudulent claims to a Federal health care program; engaging in unlawful kickback arrangements; and defaulting on health education loan or scholarship obligations.

If you are excluded by OIG from participation in the Federal health care programs, then Medicare, Medicaid, and other Federal health care programs, such as TRICARE and the Veterans Health Administration, will not pay for items or services that you furnish, order, or prescribe. Excluded physicians may not bill directly for treating Medicare and Medicaid patients, nor may their services be billed indirectly through an employer or a group practice. In addition, if you furnish services to a patient on a private-pay basis, no order or prescription that you give to that patient will be reimbursable by any Federal health care program.

For more information, see OIG's Special Advisory Bulletin entitled "The Effect of Exclusion From Participation in Federal Health Care Programs".

You are responsible for ensuring that you do not employ or contract with excluded individuals or entities, whether in a physician practice, a clinic, or in any capacity or setting in which Federal health care programs may reimburse for the items or services furnished by those employees or contractors. This responsibility requires screening all current and prospective employees and contractors against OIG's List of Excluded Individuals and Entities. This online database can be accessed from OIG's Exclusion Web site. If you employ or contract with an excluded individual or entity

I. Physician Relationships with Payers Introduction

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Chairman Weisz and members of the House Human Services Committee

HB1373 I aimed at helping to control medical costs by prohibiting the practice of paying a medical provider for referrals.

Federal law generally prohibits such practices in the Medicare and Medicaid programs with certain safe harbors. https://oig.hhs.gov/fraud/docs/safeharborregulations/012389.htm

I include a printout of the major laws effecting medical providers and an explanation of each. What I am wanting to expand is the Anti-Kickback Statute [42 U.S.C. § 1320a-7b(b)]

They prohibit kick-backs for Medicare and Medicaid but they don't prohibit such practices for private pay patients. Another big one is that a hospital for instance may require a physician to refer patients to the other providers and services of the hospital. This encourages extra tests, the use of high priced specialists when they aren't needed and so on. The testing especially puts patients at risk both physically and financially.

This is what the bill is doing, not making certain provider groups exempt as they are under federal law and does not limit itself to only government funded healthcare like the federal statute does.

The Health council is put in charge of making rules and the rules will state when more restrictive than federal law.

The middle part of the bill exempts patients so they can receive such things as samples but for instance a provider could not pay you to sit in the hospital.

The fine is in 4. Which is either $1000 or 110% of the financial benefit given the provider.

5. Exempts health care cooperates.

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North Dakota Hospital Association Est. 1934

Vision
The North Dakota Hospital Association will take an active leadership role in major Healthcare issues.

Mission
The North Dakota Hospital Association exists to advance the health status of persons served by the membership.

Testimony: 2019 HB 1373
House Human Services Committee
Representative Robin Weisz, Chairman
January 22, 2019

Good morning Chairman Weisz and Members of the House Human Services Committee. I am Melissa Hauer, General Counsel for the North Dakota Hospital Association. I am here to testify regarding 2019 House Bill 1373 and ask that you give this bill a **Do Not Pass** recommendation.

This bill would create a state anti-kickback statute in addition to the federal anti-kickback statute. The state health council would be tasked with adopting rules restricting financial relationships or payment arrangements involving health care providers if that provider benefits financially by referring a patient to another person, recommends another person, or furnishing or recommending an item or service. The rules have to be as strict as, but could be more restrictive than, the federal anti-kickback law. Health care providers who violate these provisions could be fined by the state health officer $1,000 or 110 percent of the estimated financial benefit realized, whichever is greater.

This legislation is a duplication of existing federal law, with the potential of creating even more restriction and bureaucracy in an already highly regulated industry. Federal fraud and abuse laws, such as the Physician Self-referral (Stark) Law, the False Claims Act, the Anti-Kickback Statute, the Exclusion Authorities, and the Civil Monetary Penalties Law, are broad and can result in criminal penalties, civil fines, exclusion from federal health care programs, and loss of professional licenses. It is unclear why these federal laws are not enough protection, especially in a state like North Dakota where minimal fraud exists.

Adding another regulatory burden to health care providers is unnecessary. It can be difficult to

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determine exactly what constitutes a prohibited "kickback" under federal law. It is so complex that the federal enforcement agencies have adopted regulatory "safe harbors" which provide guidance and protection to health care providers. If a business practice falls squarely within a safe harbor, it is not subject to federal liability. The federal government also issues advisory opinions that interpret existing law and regulation to further help providers understand what constitutes an illegal "kickback". The safe harbors have also been updated several times to provide additional clarification of what is and is not allowed.

The federal law is broad and regulatory guidance as well as court opinions have been, and continue to be, necessary to define payment and business practices that will not be considered kickbacks, bribes, or rebates that unlawfully induce payment by Medicare or Medicaid programs. The bill would allow the health council to eliminate existing federal safe harbors by adopting more restrictive rules. This would impose additional burden on health care providers to learn a new set of requirements that may prohibit financial and referral relationships between physicians or other providers and suppliers that the federal law allows. Providers who violate the federal anti-kickback law already face significant fines and criminal sanctions. If this bill passes, providers who violate new, more restrictive state requirements will also be subject to state-imposed fines.

This bill would create uncertainty in the state's health care business climate. It is unclear whether arrangements that met federal requirements before this bill was passed would become unlawful under newly adopted state rules. And, it is unnecessary given that there is minimal fraud in North Dakota and that there already exist broad and powerful federal laws that outlaw fraud and abuse and impose significant civil and criminal penalties for violation.

We oppose the bill as unnecessary and ask that you give it a **Do Not Pass** recommendation. I would be happy to try to answer any questions you may have. Thank you.

Respectfully Submitted,

Melissa Hauer, General Counsel
North Dakota Hospital Association