

New anti-kickback safe harbors and CMP law exceptions

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Topics to be covered

1. New (2017) anti-kickback safe harbors
2. New (2017) exceptions to the CMP law
3. Changes in provider-based billing
4. Developments in telemedicine

I. FEDERAL ANTI-KICKBACK LAW

Federal anti-kickback law makes it illegal to:

- offer, pay, solicit or receive anything of value in order to induce or reward the referral of business reimbursable under Medicare, Medicaid or other federal healthcare programs

Anti-kickback law scope

- Includes:
 - Remuneration intended to induce or reward referral of patients
 - Remuneration intended to induce or reward purchasing, leasing or ordering of any item reimbursable by a federal healthcare program

AKS safe harbors

Compliance with a safe harbor insulates a person from liability under the anti-kickback law

Common safe harbors:

- employment
- personal services
- lease of space & services

**New AKS safe harbors
1. LOCAL TRANSPORTATION**

Local transportation

Can hospitals provide taxis and transportation to patients to come to appointments or receive care?

Or is such transportation a “kickback” to use that provider, or an inducement to use the provider and a violation of the CMP law?

Local Transportation Safe Harbor Requirements

A healthcare provider may provide discounted or free local transportation to Medicare/federal patients if:

- * has policy applied consistently
- * availability not related to volume or value of business
- * not air, luxury or ambulance transportation
- * not publicly advertised
- * eligible entity bears the cost of the transport
- * only to "established patients" in 25 miles
- * to obtain medically necessary items/services

"Established patient"

- Patient who has previously attended an appointment
- Patient who has scheduled an appointment

"Established patient" requirement does not apply to entities that do not provide services such as health plans or ACOs

Who may provide transportation?

An "eligible entity":

- healthcare providers
- any individual or entity except those who primarily supply healthcare items (e.g., no DME companies or pharmaceutical companies)
- ACOs, health plans and health systems that do not directly provide healthcare are also "eligible entities"

Where can transportation be provided?

- Can transport both TO a provider or supplier of services, and back to a patient's home
- If eligible entity makes transportation available for services provided by others, can't based on referrals
 - E.g., can't transport only to drs on staff
 - But can set limits, e.g., geographic range, only primary care, only for visits in d/c plan

Type of transportation

- Need not be planned in advance
- Patients may use vouchers (rather than have transportation provided directly by eligible entity)
- No luxury transportation
- Can use Lyft/Uber but not "black" service

Shuttle service

An eligible entity can provide a shuttle service (vehicle that runs on a set route, set schedule) if:

- not air, luxury or ambulance transport
- not marketed or advertised (except posting route and schedule) and persons involved not paid on per-beneficiary transported basis
- no more than 25 miles from any stop on shuttle to a location where items/services provided (50 miles in rural area)

Shuttle service & established patient

- Shuttles not subject to established patient requirement
- Health system may offer shuttle service to public that makes stops at system's facilities but no facilities outside the system

**Anti-kickback safe harbor
2. WAIVER OF CO-PAYS**

General Medicare rule: Routine waiver of copays is an illegal kickback

- see OIG 1994 Special Fraud Alert
- allowed if documented financial hardship

Commercial insurers: Routine waiver of copays are financial fraud (because billed charge is not actual charge is patient not expected to pay all)

Waiver of co-pays now allowed in four situations: #1

1. Inpatient hospital services
 - a. Not tied to reason for admission, LOS or DRG
 - b. Waiver not part of a price reduction agreement with a third party payor (unless part of a Medicare supplemental policy)
 - c. Hospital can't claim amount as bad debt

Waiver of co-pays safe harbor #2 and 3

- 2. FQHC may waive copays for patients who qualify for subsidized services
- 3. Ambulances may waive co-pays if owned and operated by State or a subdivision, is engaged in an emergency response, and offers such to all individuals transported

Waiver of co-pays #4

- Pharmacies may waive co-pays if:
- (i) waiver or reduction not advertised or part of a solicitation
 - (ii) pharmacy does not routinely waive co-pays and waives only after determining financial need or making reasonable collection efforts (except for subsidy-eligible individuals)

II. Civil Monetary Penalties Law Beneficiary Inducements

- Civil Monetary Penalties (CMP) law:
- any person who offers or transfers to a Medicare/caid patient
 - any remuneration
 - that the person knows or should know
 - is likely to influence the selection of a particular provider or supplier of Medicare/caid items or services
 - liable for CMPs up to \$10,000 per act

What is “remuneration” under CMP?

Remuneration includes:

- waivers of copays and deductibles
- transfer of items or services for free or less than fair market value

Exceptions:

- gifts of nominal value (was \$10 per item and \$50 per patient per year – now \$15/75)
- others
- new exceptions to be discussed

Current CMP exceptions to beneficiary inducement prohibition

1. Provider can offer something of nominal value
Nominal value raised from \$10 per item or \$50 per patient in aggregate annually

- to \$15 per item
- \$75 per patient in aggregate annually

May not be cash or cash equivalents

2. Promotion of preventive services
3. Anything allowed under the anti-kickback law

Safe harbors to AKS & CMP

- Safe harbors to the anti-kickback law are incorporated by reference as exceptions to beneficiary inducements CMP
- So transportation safe harbor is not an “inducement” to a Medicare patient under the CMP law

New exceptions under CMP law

- Amend definition of “remuneration”
- Codify certain statutory exceptions added by Balanced Budget Act and ACA

CMP exceptions #1: promotes access to care

1. Exemption for remuneration that “improves a beneficiary’s ability to obtain items and services payable by Medicare/caid, and pose a low risk of harm to Medicare/caid programs by:
 - being unlikely to interfere with clinical decision-making
 - being unlikely to increase costs through overutilization or inappropriate utilization and
 - not raising patient safety or quality of care concerns

CMP exception #1 (improve ability to obtain services)

- Exception not limited to items that are medically necessary
 - As long as increase patient’s ability to obtain care, and pose a low risk of harm
- May be given before seeing a doctor if to facilitate obtaining care
 - E.g., may send patient a monitoring device to collect health data before an appointment
- Cannot be cash, cash equivalent or copay waiver

What does not qualify

- Cannot be remuneration that reward patient adherence
- May not be a reward for receiving care (e.g., movie tickets in return for attending clinic)

**CMP exception #2:
Retailer rewards programs**

Retailer may offer or give rewards for free or less than fair market value IF:

- (i) offered on equal terms to public regardless of insurance
- (ii) not tied to provision of other items or services paid by Medicare (e.g., can't condition on purchase of goods or services paid for by Medicare)

May include coupons, rebates, store merchandise, gas, frequent flyer miles, etc.

Who are retailers?

Retailers: entities that sell items directly to consumers

Includes:

- Independent or small pharmacies
- Online retailers
- Entities that sell a single category of items

Not individuals or entities that primarily provide services (doctors or hospitals)

Not included in retailer rewards

- Cannot be discounts specific to Medicare or Medicaid reimbursable items or services
 - But if can use for anything, can include Medicare or Medicaid covered items or services

**CMP exception #3:
Patients in financial need**

May offer or give items or services for free or less than fair market value to Medicaid/
Medicare beneficiaries in financial need if:
 (i) items or services are not advertised
 (ii) not tied to provision of other items or services paid for by Medicare
 (iii) reasonable connection between the items/services and patient's medical care

Financial need policy

- Must have good faith determination of the individual's financial need
- No specific documentation of financial need required
- But should have a financial assistance policy if use exception #3

Caution

Beware: complying with an exception to the beneficiary inducement provisions of the CMP does not guaranty that the arrangement will be protected from prosecution under the anti-kickback law

III. Changes in provider-based billing

Payments for services performed in provider-based facilities often more than 50% higher than payments for the same services in freestanding facilities

- the hospital may bill a facility fee (paid under OPPS)
- and doctor may bill a professional fee

Increases in provider based billing

In past seven years, the number of Medicare services provided in a hospital outpatient setting (including provider-based facilities) increased 33%

- Medpac: this increase due to hospitals purchasing freestanding facilities and converting to provider-based

What is a provider-based facility?

A facility or department of a hospital that bills as an outpatient department of hospital

- may be on-campus: within 250 yards of the main buildings of the main provider or
- off campus: more than 250 yards but within 35 miles of the main provider

Limit on new off-campus facilities

Effective January 1, 2017, only off-campus provider based facilities billing OPPS for services before November 2, 2015 (grandfathered sites) may continue to bill OPPS

- only exception: dedicated emergency departments

On-campus outpatient departments may continue to bill provider-based

Requirements for provider-based

- 1) Same licensure as main provider
- 2) Clinically integrated
- 3) Financially integrated
- 4) Held out as part of main provider
- 5) Compliance with hospital anti-dumping, nondiscrimination and safety rules, as well as Medicare payment rules (charge co-pays)

Additional provider-based requirements for off-campus

1. Off-campus facility must be 100% owned by main provider, with same governing body and under same organizational documents
2. Same level of administration and supervision
3. Within 35 miles of main provider (some exceptions allowed, e.g, rural health centers)
4. Requirement to give Medicare beneficiaries written notice of coinsurance obligations for both hospital visit and physician services

Attestation by hospitals

Hospitals may but are not required to submit an attestation to CMS that facility meets provider-based requirements

- supporting documentation required for off-campus facilities but not on-campus
- incentive to attest: if provider-based status denied, overpayments recouped only after attestation

Physician billing in provider-based facilities

Physician claim contains a place of service code showing setting where service performed

- physician office: code 11
- on-campus provider based sites: code 22
- off-campus provider-based sites: code 19 (new since January 1, 2016)

Payment to doctor differs depending on code

OIG position

MedPAC recommendations:
- eliminate provider-based designation
or
- equalize payment for same physician services in different settings
Supports MedPAC, and recommendations monitoring, attestations for all sites, and action against hospitals
(OIG report June 2016)

IV. TELEMEDICINE & LEGAL ISSUES

Licensing: practitioner must be licensed in the state in which the patient sits

Issues:
- is practitioner practicing a profession
- is this a consult with another professional

HIPAA

Initial question: is the provider a HIPAA-covered entity? (Does the provider bill electronically using HIPAA EDI transactions?)

If yes, must comply with same HIPAA requirements whether services are in-person or through telehealth

HIPAA Privacy rules

HIPAA privacy rules: must maintain privacy of protected health information (PHI)

- policies and procedures
- notice of privacy practices
- HIPAA privacy officer
- HIPAA-compliant authorizations

Rules apply to both originating and distant sites

HIPAA Security rules

Must maintain the security of any electronic protected health information (PHI) that is stored, transmitted or received electronically

- how are electronic files and images stored
- technology used for telehealth needs to ensure high level security and prevent breaches
- encryption to prevent data hacking
- do risk assessment to determine risks

HIPAA sharing of information

Technical providers who can access PHI and work on behalf of provider is a business associate

- need a business associate agreement

Telehealth involves sharing of information

- address questions about shared responsibility for managing and securing patient information generated through a telehealth encounter

Malpractice liability

- Four elements of a malpractice/negligence suit:
- duty of care
 - breach of that duty (provider didn't act as a reasonably prudent person in that situation)
 - damage to the patient
 - the provider's breach of duty caused the damage

Lawsuits in telehealth not common. Most common is radiology and failure to diagnose

Malpractice insurance

Must ensure that malpractice insurance covers telehealth

Malpractice carrier may require submission of a questionnaire regarding location, frequency and type of service provided, or pre-approval

May have to pay a surcharge or premium
Carrier may cover only with a specific state

Credentialing/privileging

Providers practicing at facilities must be credentialed by those facilities

Joint Commission allows hospitals to "privilege by proxy," i.e., accept a distant site hospital's credentialing and privileging decisions

Prescribing often requires physical exam

A physical exam should be performed BEFORE a prescription is written

Question: can an exam be done via telehealth?

- twenty states allow physical exams or evaluations to be performed by electronic means or via telehealth technologies

Some states regulate through what pharmacies can fill

Controlled substances prescribing

Ryan Haight Online Pharmacy Consumer Protection Act requires at least one in-person medical evaluation (DEA jurisdiction)

Can prescribe controlled substances via telehealth

- patient in hospital or registered clinic
- treating practitioner present
- telehealth practitioner in Indian Health Sv
- medical emergency or
- under circumstances that US AG ok's

Informed consent

Consider what type of informed consent patient must provide before telehealth used

- explain: purpose, risks, benefits, alternatives

Also consider:

- what documentation exists of consent
- where patient signs
- where documentation is maintained

Informed consent elements per Federation of State Medical Boards

Informed consent for telemedicine should include:

- Identification of physician & credentials
- Type of transmissions permitted, e.g., appointment, scheduling, prescriptions
- That physician determines if condition is appropriate for telemedicine
- Security measures, e.g., encryption
- Hold harmless if info lost with technical failures
- Express consent to forward information

AMA Telemedicine Policy

1. Establish patient relationship before services
2. Abide by state licensure & practice laws
3. Patient must have choice of provider
4. Patient has access to provider qualifications
5. Standards and scope of telemedicine services are consistent with in-person services
6. Follow evidence-based guidelines
7. Patient knows costs and any limitations
8. Collect medical history

AMA Telemedicine Policy

9. Services must be properly documented
10. Care coordination with patient's existing docs
11. Protocols for referrals for emergencies
12. Abide by laws for privacy and security of patient information
13. Physicians are responsible for supervision of non-physician providers, including:
 - protocols, conferencing & record review
 - visit sites & know competencies of providers
 - conform to state practice acts

Telemedicine trends

1. Expanding payment/reimbursement
2. Expanding use in accountable care organizations and other value-based payment arrangements
3. More activity at state level
4. Increase in telemedicine as an employee or health benefit

Questions

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