



EDUCATIONAL RESOURCES

Building a Legally Compliant Referral Network

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 PHARMACY



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Introduction



Introduction

- Competition is tough
- Margins are thin
- Referrals are key to success
- A pharmacy must enter into relationships with physicians, hospitals, DME suppliers, home health agencies, long-term care facilities, and other referral sources.
- In doing so, it is critical that the pharmacy comply with federal and state anti-fraud laws.

Legal Guidelines



Federal Anti-Kickback Statute

- It is a felony for a health care provider to knowingly and willfully offer or pay any remuneration to induce a person/entity to refer an individual for the furnishing or arranging for the furnishing of any item for which payment may be made under a federal health care program or the purchase or lease or the recommendation of the purchase or lease of any item for which payment may be made under a federal health care program.

Beneficiary Inducement Statute

- This statute prohibits a provider from offering or giving anything of value to a Medicare beneficiary that the provider knows, or should know, is likely to persuade the person to purchase an item covered by a federal health care program.
- In the preamble to the regulations implementing this statute, the OIG stated that the inducement statute does not prohibit the giving of incentives that are of “nominal value.”
- The OIG defines “nominal value” as no more than \$15 per item or \$75 in the aggregate to any one beneficiary on an annual basis.
- “Nominal value” is based on the retail purchase price of the item.

Stark Physician Self-Referral Statute

- This statute provides that if a physician has a financial relationship with an entity providing “designated health services,” the physician may not refer Medicare/Medicaid patients to the entity unless a Stark exception applies.
- Designated health services include DME; parenteral and enteral nutrients; prosthetics, orthotics, and prosthetic devices and supplies; out-patient prescription drugs; and rehab therapy services.
- One of the exceptions to Stark provides that a health care provider may provide non-cash equivalent items to a physician if such items do not exceed an annual amount established by CMS. For 2022, such amount is \$452.

Safe Harbors

- Because of the breadth of the Medicare anti-kickback statute (“AKS”), the OIG has published a number of safe harbors.
- A safe harbor is a hypothetical fact situation such that if an arrangement falls within it, then the AKS is not violated.
- If an arrangement does not fall within a safe harbor, then it does not mean that the arrangement violates the AKS. Rather, it means that the arrangement needs to be carefully scrutinized under the language of the AKS, applicable case law, and other published guidance
- Five of the safe harbors are particularly relevant to pharmacies.

Safe Harbors – Small Investment Interest

- For investments in small entities, “remuneration” does not include a return on the investment if a number of standards are met, including the following:
 - i. no more than 40% of the investment can be owned by persons who can generate business for or transact business with the entity and
 - ii. no more than 40% of the gross revenue may come from business generated by investors.

Safe Harbors – Space Rental

- Remuneration does not include a lessee's payment to a lessor as long as a number of standards are met including the following:
 - i. the lease agreement must be in writing and signed by the parties;
 - ii. the lease must specify the premises covered by the lease
 - iii. the term must be for not less than one year; and
 - iv. the aggregate rental charge must be set in advance, be consistent with fair market value, and must not take into account business generated between the lessor and the lessee.

Safe Harbors – Equipment Rental

- Remuneration does not include any payment by a lessee of equipment to the lessor of equipment as long as a number of standards are met including the following:
 - i. the lease agreement must be in writing and signed by the parties;
 - ii. the lease must specify the equipment;
 - iii. the term of the lease must be for not less than one year; and
 - iv. the rent must be set in advance, be consistent with fair market value, and must not take into account any business generated between the lessor and the lessee.

Safe Harbor – Personal Services & Management Contracts

- Remuneration does not include any payment made to an independent contractor as long as a number of standards are met including the following:
 - i. the agreement must be in writing and signed by the parties;
 - ii. the agreement must specify the services to be provided;
 - iii. the term of the agreement must be for not less than one year;
 - iv. the methodology for calculating the compensation must be set in advance, be consistent with fair market value, and must not take into account any business generated between the parties; and
 - v. the services performed must not involve a business arrangement that violates any state or federal law.

Safe Harbors – Employees

- Remuneration does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made, in whole or in part, under Medicare or under a state health care program.

Advisory Opinions

- A health care provider may submit to the OIG a request for an advisory opinion concerning a business arrangement that the provider has entered into or wishes to enter into in the future.
- In submitting the advisory opinion request, the provider must give to the OIG specific facts.
- In response, the OIG will issue an advisory opinion concerning whether or not there is a likelihood that the arrangement will implicate the anti-kickback statute.
- <https://oig.hhs.gov/compliance/advisory-opinions/>

Special Fraud Alerts & Special Advisory Bulletins

- From time to time, the OIG publishes Special Fraud Alerts and Special Advisory Bulletins that discuss business arrangements that the OIG believes may be abusive and educate health care providers concerning fraudulent and/or abusive practices that the OIG has observed and is observing in the industry.
- <https://oig.hhs.gov/compliance/alerts/>

States

- All states have enacted statutes prohibiting kickbacks, fee splitting, patient brokering, or self-referrals.
- Some state anti-fraud statutes only apply when the payer is a government health care program.
- Other state anti-fraud statutes that apply regardless of the identity of the payer.
- All states have a set of statutes and regulations that are specific to pharmacies.

W-2 vs. 1099

- The OIG has repeatedly expressed concern about percentage-based compensation arrangements involving 1099 independent contractor sales agents.
- In Advisory Opinion No. 06-02, the OIG stated that “[p]ercentage compensation arrangements are inherently problematic under the Anti-Kickback Statute, because they relate to the volume or value of business generated between the parties.”

W-2 vs. 1099

- A number of courts have held that marketing arrangements are illegal under the anti-kickback statute and are, therefore, unenforceable.
- For example, the 1996 Florida *Medical Development Network* case involved an agreement wherein a durable medical equipment supplier agreed to pay an independent contractor marketing company (the “Marketer”) a percentage of the DME supplier’s sales in exchange for marketing its products to physicians, nursing homes, and others.

W-2 vs. 1099

- When the DME supplier breached the contract, the Marketer sued, and the DME supplier defended on the ground that the agreement was illegal under the anti-kickback statute.
- A Florida appeals court agreed and affirmed the trial court's ruling, holding that the agreement was illegal and unenforceable because the Marketer's receipt of a percentage of the sales it generates for the DME supplier violated the federal anti-kickback statute.

W-2 vs. 1099

- In recent years, there have been a number of enforcement actions involving commission payments to independent contractors.
- Additionally, the OIG has taken the position that even when an arrangement will only focus on commercial patients and “carve out” beneficiaries of federally-funded health care programs, the arrangement will still likely violate the anti-kickback statute.



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Utilization of a Marketing Company

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Utilization of a Marketing Company: Be Aware of Kickback Problem

- In the real world, it is common for a business to “outsource” marketing to a marketing company.
- Unfortunately, what works in the real world often does not work in the health care universe. An example of this has to do with marketing companies.
- If a marketing company generates patients for a pharmacy, when at least some of the patients are covered by a government health care program, then the pharmacy cannot pay commissions to the marketing company.
- Such payment of commissions will violate the AKS.

Utilization of a Marketing Company: Be Aware of Kickback Problem

- The only way that an independent contractor can be paid for marketing or promoting Medicare-covered items or services is if the arrangement complies with the Personal Services and Management Contracts safe harbor.

Utilization of a Marketing Company: Be Aware of Kickback Problem

- In Advisory Opinion No. 99-3, the OIG stated:
 - Sales agents are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals, typically manufacturers, or other sellers (collectively, “Sellers”).
 - Accordingly, any compensation arrangement between a Seller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the anti-kickback statute, irrespective of the methodology used to compensate the agent.

Utilization of a Marketing Company: Be Aware of Kickback Problem

- In Advisory Opinion No. 99-3, the OIG further stated:
 - Moreover, because such agents are independent contractors, they are less accountable to the Seller than an employee.
 - For these reasons, this Office has a longstanding concern with independent sales agency arrangements.

Utilization of a Marketing Company: Be Aware of Kickback Problem

- Further, in its response to comments submitted when the safe harbor regulations were originally proposed, the OIG stated:
 - [M]any commentators suggested that we broaden the [employee safe harbor] to apply to independent contractors paid on a commission basis.
 - We have declined to adopt this approach because we are aware of many examples of abusive practices by sales personnel who are paid as independent contractors and who are not under appropriate supervision.

Utilization of a Marketing Company: Be Aware of Kickback Problem

- The OIG further stated:
 - We believe that if individuals and entities desire to pay a salesperson on the basis of the amount of business they generate, then to be exempt from civil or criminal prosecution, they should make these salespersons employees where they can and should exert appropriate supervision for the individual's acts.

What a Pharmacy Can Spend on (or Pay to) a Physician

- A physician is a referral source to the pharmacy.
- The physician refers patients who are covered by a government health care program, who are covered by commercial insurance, or desire to pay cash.
- If a pharmacy pays money to a physician for services, or provides meals, gifts and entertainment to a physician, then both the pharmacy and the physician need to comply with the federal and state laws that govern these arrangements.

What a Pharmacy Can Spend on (or Pay to) a Physician

- While the Stark non-monetary compensation exception allows a pharmacy to spend up to a set amount per year (e.g., \$452 in 2022) for non-cash/non-cash equivalent items for a physician, the Medicare anti-kickback statute does not include a similar exception.
- Nevertheless, if the Stark exception is met, it is unlikely that the government will take the position that the non-cash/non-cash equivalent items provided by the pharmacy to the physician violate the AKS.

What a Pharmacy Can Spend on (or Pay to) a Physician

- In addition to complying with Stark and the AKS, the pharmacy and the physician also need to comply with applicable state law.
- Even though the pharmacy and the physician will need to confirm this, it is likely that compliance with the non-monetary compensation exception will avoid liability under state law.

What a Pharmacy Can Spend on (or Pay to) a Physician

- While the Stark non-monetary compensation exception applies to expenditures on behalf of a physician, the exception does not apply to expenditures on behalf of the physician's staff.
- In fact, Stark does not apply to the physician's staff. Expenditures on behalf of the physician's staff must be examined in light of the AKS.

What a Pharmacy Can Spend on (or Pay to) a Physician

- Separate from furnishing gifts and entertainment, and subsidizing trips, the pharmacy can pay the physician for legitimate services.
- For example, if the pharmacy has a legitimate need for a Medical Director, then the pharmacy and physician can enter into a Medical Director Agreement that complies with both the PSMC safe harbor to the AKS and the Personal Services exception to Stark.

What a Pharmacy Can Spend on (or Pay to) a Physician

- Another legitimate way for money to exchange hands between a pharmacy and a physician is for the physician to rent space to the pharmacy or vice versa.
- The rental arrangement needs to comply with the Space Rental safe harbor to the AKS.
- This safe harbor is similar to the PSMC safe harbor.

What a Pharmacy Can Spend on (or Pay to) a Physician

- Among other requirements:
 - the parties must execute a written lease agreement that has a term of at least one year;
 - the rent paid must be fixed one year in advance (e.g., \$48,000 over the next 12 months), and
 - the rent must be fair market value.
- The rental arrangement needs to also comply with the Space Rental exception to Stark; this exception is similar to the Space Rental safe harbor to the AKS.

Paying Physician to Provide Education Program

- Special Fraud Alert: Speaker Programs (November 2020)
 - OIG is skeptical about the educational value of such programs
 - Remuneration to the speaker may skew clinical decision making in favor of the speaker's financial interest instead of the patients.
 - Studies have shown that speakers who receive remuneration from a company are more likely to prescribe or order that company's products.

Paying Physician to Provide Education Program

- It is permissible for a pharmacy to pay a physician to present an education program if the following requirements are met:
 - The program is substantive and valuable to the audience.
 - The compensation paid to the physician is the fair market value equivalent of the time and effort the physician expended to (i) prepare for the program and (ii) present the program.

Criminal Case

- A number of executives and employees of Insys Therapeutics, Inc. were convicted of violating the AKS.
- According to a Department of Justice (“DOJ”) statement, Insys used bogus educational events as a “cover” for paying kickbacks to physicians in exchange for their increased prescriptions of Subsys®, a spray version of the opioid fentanyl.
- The DOJ alleged that Insys arranged sham “speaker programs,” which were billed as gatherings of physicians to educate them about Subsys®.
- In reality, according to the DOJ, the events - usually held at high-end restaurants - mostly consisted of friends and co-workers who lacked the ability to prescribe the drug, and there was no educational component.

Criminal Case

- According to the DOJ, the “speakers” were physicians who were paid fees ranging from \$1000 to several thousand dollars to attend the dinners.
- The indictment says that these payments were kickbacks to the speakers “who were prescribing large amounts of Subsys® and to incentivize those [physicians] to continue to prescribe Subsys® in the future.”

Criminal Case

- Here are the “takeaways” from this criminal case:
 - Before the pharmacy provides “anything of value” to a physician, the pharmacy needs to consult with a health care attorney to ensure that the arrangement does not violate the AKS or Stark.
 - “Anything of value” can be a payment of money, it can be a trip, it can be a set of golf clubs, it can be tickets to a Springsteen concert, and it can be services that the physician would normally have to perform himself.

Criminal Case

- “Takeaways” (Cont’d):
 - It is permissible for a pharmacy to enter into a Medical Director Agreement (“MDA”) with a physician who also refers Medicare patients to the pharmacy. The MDA needs to comply with the Personal Services and Management Contracts safe harbor to the AKS and with the Stark Personal Services exception. Among other requirements, (i) the MDA must be in writing and have a term of at least one year, (ii) the physician must render valuable (not “made up”) services to the pharmacy, (iii) the methodology for calculating the compensation paid by the pharmacy to the physician must be fixed one year in advance, and (iv) the compensation must be the fair market value (“FMV”) equivalent of the physician’s services.

Criminal Case

- “Takeaways” (Cont’d):
 - If a pharmacy is going to pay a physician to put on an education program, then it must pass the “smell test.” The physician must be qualified to make the presentation, the physician must actually make the presentation, the presentation topic must be substantive and timely, the audience must be in the position of benefitting from the presentation, and the compensation to the physician must be FMV.
 - If a pharmacy submits a claim to a government program that arises out of an improper arrangement with a physician, then the claim is “tainted” and becomes a false claim. Penalties under the FCA can be massive.

Collaboration With Hospital to Prevent Readmissions

- Hospital Readmissions Reduction Program: if a patient is readmitted after discharge within a certain period of time, for a particular disease, then the hospital can be subjected to future payment reductions for Medicare.
- Hospital can contract with a pharmacy to monitor/work with discharged patients so that they are not readmitted soon after being discharged.

Paying for a Facility's EHR

- Many pharmacies work with skilled nursing facilities ("SNFs") and custodial care facilities (collectively referred to as "Facilities").
- A Facility is a "referral source" to the pharmacy. Even though the Facility may give "patient choice," if the pharmacy dispenses a drug to a Facility patient, the law considers the patient to be a "referral" from the Facility.
- If the pharmacy gives "anything of value" to the Facility, then the pharmacy is at risk of being construed to be "paying for a referral"; hence, a "kickback."

Paying for a Facility's EHR

- The federal anti-kickback statute ("AKS") applies to any patient covered by a federally funded health care program.
- The AKS prohibits the pharmacy from giving anything of value to a referral source in exchange for (i) referring, or arranging for the referral of, a federally funded health care program patient to the pharmacy or (ii) recommending the purchase of a product that is paid for by a federally funded health care program.
- Under the AKS, the party providing something of value (the pharmacy) and the party receiving something of value (the Facility) are both liable.

Paying for a Facility's EHR

- Separate and apart from the AKS, each state has its own anti-kickback statute.
- Some state anti-kickback statutes apply only when the payer is the state Medicaid program.
- Other state anti-kickback statutes apply even if the payer is commercial insurance or a cash-paying patient.
- In order for a Facility to serve Medicare and Medicaid patients, federal law imposes a number of requirements on the Facility.
- These requirements cost the Facility money in order to comply.
- One such requirement is for the Facility to have a pharmacy perform a monthly drug regimen review ("DRR") on each patient.

Paying for a Facility's EHR

- Electronic medication administrative records (“eMARs”) are not required for DRR; hard copy records are acceptable. Nevertheless, a Facility may desire to utilize eMAR software (“Software”) for DRR and for other purposes.
- The Facility and a pharmacy (that receives referrals from the Facility) may wish to enter into an arrangement in which the pharmacy pays for the Software. It is at this juncture that the Facility and pharmacy find themselves on the proverbial "slippery slope."
- Assume that the pharmacy receives referrals from the Facility and desires to pay for the Software. By virtue of paying for the Software, the pharmacy is providing “something of value” to the Facility; hence, the AKS is implicated.

Paying for a Facility's EHR

- The Office of Inspector General (“OIG”) has published a number of “safe harbors” to the AKS.
- If an arrangement complies with all of the elements of a safe harbor, then as a matter of law the AKS is not violated. If an arrangement does not comply with all of the elements of a safe harbor, then it does not mean that the AKS is violated.
- Rather, it means that the arrangement must be carefully scrutinized in light of the language of the AKS, court decisions, and other published guidance.

Paying for a Facility's EHR

- The applicable safe harbor is the Electronic Health Records safe harbor (“EHR Safe Harbor”).
- It states that an entity may donate software and training services “necessary and used predominantly to create, maintain, transmit, or receive electronic health records” if a number of requirements, set out in the safe harbor, are met.

Products to LTCF

- Separate and apart from providing EHR software, it is not uncommon for a LTCF to request a pharmacy to provide iPads, drug carts, sheets and pillows, etc.
- Any of these products constitute “something of value” being delivered to a referral source; hence, the AKS is implicated.

Products to LTCF

- It is permissible for a pharmacy to deliver iPads to a LTCF only if (i) title to the iPads remains with the pharmacy and (ii) the LTCF can only use the iPads in its interactions with the pharmacy.
- It is permissible for a pharmacy to deliver a drug cart a LTCF only if (i) title to the drug cart remains with the pharmacy and (ii) the LTCF can only use the drug cart for drugs dispensed by the pharmacy.
- The pharmacy cannot deliver items (such as sheets and pillows) that (i) are designed to save expenses for the LTCF and (ii) are not used exclusively to facilitate the services provided by the pharmacy.

Loan/Consignment Closets

- Assume that the pharmacy provides DME (e.g., braces and splints). A pharmacy may place inventory in a hospital or physician office. The inventory must be for the convenience only of the hospital's/physician's patients and the hospital/physician cannot financially benefit, directly or indirectly, from the inventory.
- If a pharmacy pays rent for a space in which the consigned inventory is placed, then the arrangement should comply with the Space Rental safe harbor.

Preferred Provider Agreement

- The pharmacy can enter into a Preferred Provider Agreement with a hospital whereby, subject to patient choice, the hospital will recommend the pharmacy to its patients who are about to be discharged.
- The pharmacy can enter into a similar type of Preferred Provider Agreement with a physician, home health agency, long term care facility, wound care center, or other type of provider.

Employee Liaison

- A pharmacy may designate an employee to be on a facility's premises for a certain number of hours each week.
- The employee may educate the facility staff regarding services the pharmacy can offer on a post-discharge basis.
- The employee liaison may not assume responsibilities that the facility is required to fulfill.
- Doing so will save the facility money, which will likely constitute a violation of the AKS.

Medical Director Agreement

- A pharmacy can enter into an independent contractor Medical Director Agreement with a physician.
- The MDA must comply with the (i) Personal Services and Management Contracts safe harbor to the AKS and (ii) the Personal Services exception to the Stark physician self-referral statute.
- Among other requirements:
 - The MDA must be in writing and have a term of at least one year.
 - The physician must provide substantive services.
 - The methodology for calculating the compensation to the physician must be fixed one year in advance and be the fair market value equivalent of the physician's services.

Renting Space

- A pharmacy can rent space to/from a physician so long as the rental agreement complies with the
 - (i) Space Rental safe harbor to the AKS and
 - (ii) space rental exception to Stark.
- Among other requirements:
 - The rental agreement must be in writing and have a term of at least one year.
 - The rent must be fixed one year in advance and be fair market value.
- A pharmacy can rent space to/from a non-physician referral source so long as the rental agreement complies with the Space Rental safe harbor to the AKS. See the preceding sub-bullets.

Joint Venture

- Definition
 - A joint venture arises when two or more individuals/entities own something together.

Joint Venture With Hospital

- A hospital and a pharmacy can jointly set up and own a pharmacy (“JV Pharmacy”) so long as the JV Pharmacy is not a “sweetheart deal” for the hospital.
 - Ideally, the JV Pharmacy will comply with the Small Investment Interest safe harbor to the AKS.
 - If the safe harbor cannot be met, then the requirements of the OIG’s 1989 Special Fraud Alert (“Joint Ventures”) and April 2003 Special Advisory Bulletin (“Contractual Joint Ventures”) must be met.

Joint Venture With Physician

- When forming a joint venture with a physician, then not only must the arrangement comply with (i) the Small Investment Interest safe harbor or (ii) the 1989 Special Fraud Alert/April 2003 Special Advisory Bulletin, but the arrangement must comply with Stark.
 - If the JV Pharmacy is located in a rural area, then the physician can refer Medicare/Medicaid patients to the JV Pharmacy.
 - If the JV Pharmacy is not located in a rural area, then the physician cannot refer Medicare/Medicaid patients to the JV Pharmacy.

Avoiding Sham Clinical Studies

- In a sham clinical study program, the physician refers patients to the pharmacy. The pharmacy provides prescription drugs to the patients.
- The physician “collects data” from the patient (e.g., “After using the drug, from a scale of one to ten, what is your pain level?”).
- The physician shares the information with the pharmacy. The information is rudimentary, the pharmacy does not need it, and it is the same information that the pharmacy can secure itself.
- The pharmacy pays the physician \$____ per patient per month.

Avoiding Sham Clinical Studies

- Sham clinical studies violate the AKS.
- The pharmacy may argue that it is not paying for referrals but is paying for legitimate services.
- However, a number of courts have enumerated the “one purpose” test. This test states that if one purpose behind a payment is to induce referrals, then the AKS is violated even if the principal purpose is to pay for legitimate services.
- With sham clinical studies, there is no question that “one purpose” behind the payments is to induce referrals. In fact, the primary purpose of the payments is to induce referrals.
- Assume that the physician refers no patients to the pharmacy who are covered by a government health care program. The pharmacy will need to look at its state’s AKS.

Stark Rural Provider Exception

- In entering into an arrangement with a physician in a rural area, the pharmacy needs to focus on the rural provider exception.
- The rural provider exception states that an ownership interest by a physician in a rural provider is not considered a financial relationship under Stark.
- Rural providers are defined as those that furnish at least 75% of the designated health services (“DHS”) they provide to residents of a rural area.
- Thus, whether this exception applies depends on whether at least 75% of the patients that the pharmacy’s services are located within a rural area.

Stark Rural Provider Exception

- “Rural area” is defined as “an area that is not an urban area as defined in 42 CFR 412.62(f)(1)(ii) which states that “the term urban area means a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget”
- Therefore, any area that is not an MSA or a NECMA is considered to be a rural area.
- So long as no less than 75% of the services that the pharmacy furnishes is to patients in a rural area, the rural provider exception applies to the pharmacy, regardless of where the pharmacy is located.

Stark Rural Provider Exception

- The current list of MSAs can be found on the U.S. Census Bureau website. A town might fall within a *Micropolitan* Statistical Area, which is defined as an urban cluster of at least 10,000 but less than 50,000 people.
- In regard to whether a *Micropolitan* Statistical Area could be considered a “rural area” under the definition of Stark, the Stark II, Phase III implementation final rule states: “**Micropolitan Statistical Areas are not within MSAs; thus, for purposes of the physician self-referral rules, Micropolitan Statistical Areas are not considered urban and are, therefore, rural areas.**”
- So long as the pharmacy satisfies the Stark “rural provider” exception, then a physician can have an ownership in the pharmacy and can refer Medicare, Medicare Advantage and Medicaid patients to the pharmacy.

Questions?





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Thank you

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