Hospital-Physician Alignment and Integration: Current Strategic and Regulatory Compliance Concerns

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Presentation Overview

► Alignment Trends
► Common Legal Concerns
► Employment
► Professional Services Agreement
  ● Medical Directorships
  ● On-Call Arrangements
► Clinical Co-Management
Hospital-Physician Alignment

► Hospital Goals

- Create or Expand Access to Services
- Continuity/Coordination of Care
- Market Share / ACO Positioning
- Enhance Quality/ Patient Experience
- Achieve Efficiencies
- Expanded Clinical Expertise / Branding
- EMTALA or Other Compliance Requirements
Hospital-Physician Alignment

► Physician Goals

- Profit or Income Stability /Increase
- Control or a Voice in Decision Making
- ACO Positioning
- Access to Capital
- Market Positioning
- Co-Branding
- Personal Prestige
- Fear of Being Left Out/Independent
Contracting With Physicians
Principal Regulatory Concerns

- Anti-kickback law
- Stark law
- Insurance laws
- Antitrust laws
- Civil monetary penalties (CMP) law (prohibiting payments to reduce services)
- False Claims Acts
- Tax exempt IRS laws

Current and evolving physician compensation models present legal challenges under fraud and abuse and other laws.
Common Legal Concerns

► Stark Law
► Anti-kickback Statute
► Internal Revenue Code/Tax Exempt Status Laws
► Gainsharing Civil Monetary Penalty Law
Stark Law

► Prohibits physician from referring to an entity for “designated health services” (DHS) payable by Medicare if physician has a “financial relationship” with the entity UNLESS:

► Arrangement satisfies **ALL** requirements of Stark exception
► Exceptions for common compensation arrangements
  ● **Employment**
  ● **Personal services**
  ● **Fair market value**
  ● **Indirect compensation**
Stark Law (cont’d)

- DHS include **ALL** inpatient and outpatient hospital services
- Strict liability (no intent to violate required)
- Financial relationships include both compensation and ownership.
- Prohibits DHS entity from billing for services to Medicare if financial relationship is non-compliant
- Compensation exceptions require compensation at fair market value ("FMV")
Stark Law Example – Employment

- UNLESS, satisfies Employment Exception
Stark “Bona Fide” Employment Exception
(42 CFR 411.357(c))

Except amount paid by employer to bona fide employee physician for services if:

- Employment for identifiable services
- Payment is consistent with FMV of the services and;
- Payment is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician
- Payment is under an agreement that would be commercially reasonable even if no referrals were made to the employer
- Payment can take the form of a productivity bonus based on services personally performed by the physician
Stark and Commercial Reasonableness

Commercially reasonable means: Would a prudent person do the deal even if no referrals?

- Consider business purposes judgment factors
  - Strategic objectives
  - Demonstrated community need for specialty or service
  - Objective to add or expand services to community or segment of patients (e.g., indigent, submarket)
  - Quality improvement goals
  - Unique skills of the physician
Anti-Kickback Statute (42 USC 1320a-7b(b))

- **Criminal law** prohibits the knowing and willful offer, payment, solicitation or receipt of remuneration (i.e., anything of value) to induce or reward, referrals of items or services payable by federal health care programs.

- Violation requires intent to illegally induce (even one purpose is to give/receive remuneration to induce referrals).

- Parties on both sides of an improper “kickback” are liable (felony up to 5 years prison and/or $25,000 fine), civil administrative penalties.

- Statutory exception for employment.
Anti-Kickback Safe Harbors

- Some safe harbors require payment at FMV
- The reason safe harbors are OK is if ALL criteria are met
  - Commercially reasonable (i.e., intrinsic commercial value to purchaser) items or services
  - Exchanged for FMV
  - *Government says little risk of fraud and abuse!*
Anti-Kickback Employment Exception and Safe Harbor (42 USC 1320a-7b(b); (42 CFR1001.952(i))

- Regulatory safe harbors protect qualifying arrangements from prosecution if **ALL** safe harbor requirements are met.
- Anti-kickback statute allows “any amount paid by an employer to an employee” for employment in the provision of covered items or services (i.e., covered by Medicare or Medicaid).
- Employee must be “bona fide” under the IRS test at 26 USC 3121(d)(2), which requires:
  - Behavioral control
  - Financial control
  - Specified relationship factors
  - **DOES NOT REQUIRE COMPENSATION TO BE FMV**
Anti-Kickback Risk Zone

► If fail to satisfy exception or safe harbor
  ■ Facts and circumstances analysis
  ■ Intent of parties will be scrutinized
  ■ **IN THE GREY RISK ZONE**

*RISKY BUSINESS!*
IRS Tax Exempt Status (IRC 501(c)(3))

IRC 501(c)(3) entities are prohibited from operating other than for charitable purposes and no part of net earnings can inure to the benefit of private individuals:

- Private benefit/private inurement prohibits payments in excess of FMV
- Total physician compensation package for actual physician services rendered must be reasonable for geographic market and physician specialty; use compensation studies
- Total compensation includes base salary, bonus, fringe benefits, and deferred compensation
- See also IRS Health Care Provider Reference Guide (2003) at p.18; Rev Proc 2001-4
IRS Intermediate Sanctions (IRC § 4958)

- If payment is to “disqualified person” may be “excess benefit” transaction:
  - Excise tax if payment exceeds FMV
  - "Disqualified persons” can include physicians if they have actual substantial influence or control over decisions (e.g., key medical director/department chair, voting board member)
  - Requires board/delegated committee to approve arrangement following “rebuttable presumption” procedure
- Approved in advance by board/committee excluding anyone with conflict of interest
- Received and relied on appropriate comparability data
- Adequately documented basis for decision concurrently
Enforcement climate is increasingly focused on FMV and commercial reasonableness.
IRS and FMV

IRS View of FMV:

- Price at which property would change hands between a hypothetical willing and able buyer and hypothetical willing and able seller acting at arms’ length in an open and unrestricted market when neither is under compulsion to buy or sell, and when both parties have reasonable knowledge of relevant facts (Rev Rule 59-60)

- Reasonable compensation is the amount that would ordinarily be paid for like services by like enterprises under like circumstances (IRC Section 162)
Stark Definition of FMV

FMV means:

- Value in arm’s length transactions, consistent with the general market value.

- General market value means the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, at the time of the service agreement.

- Fair market price is generally based on bona fide comparable services agreements, where the compensation has not taken into account the volume or value of anticipated or actual referrals.
Stark and FMV (42 CFR 411.351)

- Stark II, Phase III approved survey benchmarking:

  “reference to multiple, objective, independently published salary surveys remains a prudent practice” and FMV may vary based on nature of transaction, location, and other factors.” 72 Fed Reg 51012, 51015 (Sept. 5, 2007)

- Stark II, Phase III discussed administrative versus clinical services:

  “FMV hourly rate may be used to compensate physicians for both administrative and clinical work, provided that both are FMV for the type of services, and FMV for administrative services may be different than for clinical services. 72 Fed Reg 51012, 51016 (Sept. 5, 2007)
Summary - Principle Regulatory Concerns

► No purpose/intent of payment to induce or reward referrals
► Not taking into account the value or volume of referrals or other business generated
► Commercial reasonableness
► No payments to reduce or limit services to Medicare or Medicaid enrollees
► FMV
► Whistleblowers
Stark Law Penalties

- Disallowance of all Medicare payments made to the hospital as a result of referrals from the physician with whom the hospital had the non-compliant relationship (e.g., expired Medical Director Agreement)

- $15,000 per violation

- Possible False Claims liability $11,000 per claim and treble damages

- Possible exclusion from Medicare/Medicaid
Stark/Anti-Kickback/IRS Penalties

- Anti-kickback and Tax Exempt penalties include:
  - Fines and penalties, including imprisonment
  - IRS intermediate sanctions excise taxes on “disqualified persons” and management

- Reputational risk

- Diversion of organizational resources to addressing investigations, prosecutions and resolution of non-compliance

- Responsible Corporate Officer Doctrine can mean personal criminal liability and/or exclusion from federal health care programs
Strategy #1 – Hospital Employment of Physicians

► Overview

- Hospital hires a licensed physician to provide professional medical services on behalf of hospital directly to the community. Hospital engages physician pursuant to an employment contract, typically including a covenant not to compete.

- Often done in conjunction with practice acquisition of physician’s practice assets.
Stark Law Example Employment

- UNLESS, satisfies Employment Exception
Must Meet Stark Employment Exception

- Employment for identifiable services
- Payment consistent with FMV for services
- Payment does not “take into account” volume or value of (DHS) referrals by physician
- Agreement is “commercially reasonable” even if no referrals made by physician to employer
- Can include productivity bonus based on services personally performed by physician
Anti-Kickback and IRS Requirements

► Try to meet AKS safe harbor
► Meet IRS Fair exception test
  ■ Follow rebuttable presumption
Employment – Compliance Considerations

► Compensation Model Options
  - Salary
  - Productivity-based (i.e. wRVU’s; collections)
  - Revenue less expense
  - Per shift

► Typical Valuation Methodologies
  - Survey benchmarking (Sullivan Cotter, MGMA, AMGMA)
Employment – Compliance Considerations

- Red Flags Suggesting Risky Arrangement
  - Compensation in excess of FMV (or above 90th percentile)
  - Failure to include all forms of compensation or remuneration (e.g., benefits)
  - Compensation disproportionate to productivity
  - Arrangement not commercially reasonable
Small Town Midwestern Hospital - Employment

► Hospital recruits and employs a few (5) specialist physicians, some from local groups and some new recruits

► Hospital has difficulty recruiting specialists to Midwest small town
Small Town Midwestern Hospital – Employment (cont’d)

► Hospital pays specialists high end salaries (up to $1.8M) but thinks they are worth it

► Compensation consistent with approved compensation plan, based on work personally performed and reflects physicians’ exceptionally high level of productivity
Small Town Midwestern Hospital – Employment (cont’d)

► What went wrong?
► Employment Agreements

■ Competing physician practice sued in state court for “unfair business practices” claiming Hospital was overcompensating the specialists

■ Government gets wind and brings its own Stark/FCA case alleging compensation in excess of FMV and not commercially reasonable (Stark problem)

■ Government allegedly hires its own valuation expert, which supports its view that compensation was well in excess of FMV and not commercially reasonable
Small Town Midwestern Hospital – Employment (cont’d)

► Small Town Midwestern Hospital = Covenant Medical Center, Waterloo, IA

► Paid $4.5 Million in 2009 to settle alleged Stark/FCA violations

► Government investigation alleged physicians were highest paid hospital employed specialists in Iowa and among highest paid in the country (not FMV and not commercially reasonable) from 2005 - 2008
Small Town Midwestern Hospital – Employment (cont’d)

- Wake up call that Government focused on hospital employment of physicians to make Stark cases; bootstraps into FCA based on failing FMV and commercial reasonableness
- Government never disputed that physicians performed services, were highly qualified and productive
- Underscores importance of proper legal review and independent FMV determination, even for employment arrangements
- Covenant settled to “avoid the uncertainty of litigation”
Southern Small Town Hospital Slip Up-Employment

- SSTH learns that surgeons on its medical staff may be buying into a freestanding ASC
- SSTH offers surgeons part-time employment for outpatient surgeries only; surgeons keep office and inpatient practice
- SSTH offers full-time benefits (malpractice insurance, family health insurance, cell phones, CME, etc.)
- One surgeon doesn’t want to take SSTH’s offer, but decides to do something else…
Southern Small Town Hospital
Slip Up-Employment (cont’d)

► What Went Wrong?

■ Employment Agreements
  ► Unusual part-time arrangement
  ► Full-time benefits for part-time employees
  ► Defensive move
  ► Hospital knew it would lose money on the arrangements; paying physicians 131% of net collections; productivity compensation at 80% collections starting on first dollar
  ► Government alleged not FMV and not commercially reasonable
  ► Government hired its own valuation expert who testified at trial compensation not FMV
Southern Small Town Hospital Slip Up-Employment (cont’d)

» SSTH = Tuomey Healthcare System, Sumter, SC

» Whistleblower surgeon brought case to the Government; brought Stark, AKS, FCA case

» After 4 week trial, in March, 2010, federal jury found Tuomey violated Stark but did not submit false claims; Judge ordered Tuomey to pay $44.8 Million in Stark damages

» Court granted Government a new trial on FCA issue in August, 2010; Tuomey appeals October, 2010 [case not yet resolved]
Covenant and Tuomey Lessons Learned?

► Even common arrangements, such as employment, can result in major settlements or judgments

► Hospital employment of physicians is increasingly common, but not necessarily safe

► Regulators are getting smart about issues of FMV and commercial reasonableness

► If deal is “too good to be true” it’s probably a legal risk

► FMV valuation opinions help, but are not bullet proof
Strategy #2 - Personal Services Agreements

Overview

- Hospital engages a physician medical director to provide administrative services necessary for hospital operations, accreditation, management, etc. and requiring physician experience.

- Hospital engages physicians to provide call coverage, or to staff professional clinic or panel.

- Hospital develops co-management arrangement with physician group or specialty.
Stark Personal Services Exception
(42 CFR 411.357(d))

 ► Excepts payment to physician (or group practice) if:
  ■ **Written agreement** signed by the parties, specifying the services
  ■ Agreement **covers all services** to be furnished by physician (or cross references other service arrangements or references master list)
  ■ Aggregate services do not exceed **reasonable and necessary for the legitimate business purpose**
  ■ **Term is for at least one year** and if terminated with or without cause parties may not enter into similar arrangement during first year of original term
  ■ Compensation is “**set in advance**” and does not exceed **FMV** and is not determined in manner that takes into account the volume or value of referrals or other business generated between the parties
  ■ Services do not involve counseling or promotion of arrangements that violate federal or state laws
  ■ 6 month holdover permitted after expiration if all above are met
Stark Personal Services Exception (42 CFR 411.357(d))

Key terms to consider:

- “Set in advance” requires compensation (including per-unit of service based amount or specific formula for calculation compensation) to be stated in agreement BEFORE the services are performed. 42 CFR 411.354(d)(1)

- Percentage-based, per-click, per time period, or other formulas are “set in advance” under Stark

- Stark II Phase I commentary clarifies that:
  - Formula must be “set forth in sufficient detail” to allow “objectively verified”, and
  - Cannot be changed during term in manner that takes into account the volume or value of referrals
  - Single fee schedule (or percentage of fee schedule) uniformly applied to all services is “set in advance”; percentage of revenues, collections, or expenses is “set in advance” (66 Fed. Reg. at 856, 877 (January 4, 2001))
Anti-Kickback Personal Services Safe Harbor
(42 CFR 1001.952(d))

Protects payment to physician or group practice if:

- **Written agreement** signed by parties, specifying the services

- Agreement **covers all services** to be furnished and specifies the services

- If part time or sporadic services, agreement includes a **schedule**, including exact length and compensation
Anti-Kickback Personal Services Safe Harbor (42 CFR 1001.952(d))

- Term is for at least **one year**
- Aggregate compensation for term is “**set in advance**”, and **FMV**, arm’s-length, and does not take into account the volume or value of referrals or other business generated by the parties
- Aggregate services do not exceed what is **commercially reasonable**
Medical Directors and Personal Service Agreements

► Legal Considerations

■ Stark/AKS: Personal Services Exception/Safe Harbor or Stark FMV Exception

■ Risk Areas

► Ensure aggregate services do not exceed what are reasonably necessary for legitimate business purposes (commercially reasonable)
► No or poor documentation of services
► Little/no actual services required
► Stacking/Impossible day
Medical Directors and Personal Service Agreements (cont’d)

► Compensation does not match agreement or services
► Numerous directorships with apparent overlap
► Services provided are unnecessary and/or undocumented
► Fee based on clinical opportunity cost or practice overhead
► Access to federal health care patients is remuneration (Christ Hospital case)
Medical Directors and Personal Service Agreements (cont’d)

- Compensation Model Options
  - Based on market hourly rates for medical director services or professional services
  - Per shift
  - Stipend
  - wRVU for professional services
On-Call Arrangements

► Overview

- Hospital engages a physician or physician group to provide guaranteed clinical coverage at its facility(s), including Emergency Department, inpatient service (e.g., OB)
- May be restricted (on-site) or unrestricted (off-site with obligation to call in/report in within specified time)
On Call Arrangements

Legal Considerations

- Generally comply with same laws as Medical Directors and Personal Services Agreements (Stark/AKS personal services exception/safe harbor, FMV, commercially reasonable)

- Also consider factors in OIG Advisory Opinions on call coverage
On Call Arrangements

Legal Considerations/Factors to consider

- History of payment/non-payment for on-call services
- Refusal of physicians to provide uncompensated call
- Document reasons for on-call pay
- Overlapping services/stacking (cannot pay for call if at same time as other services, e.g., professional or medical director)
On Call Arrangements

Legal Considerations/Factors to consider (cont’d)

- Selection of physicians; best to offer to all on staff in specialty
- No intent to induce referrals (AKS)
- No double payment for services (e.g., hospital pays for pro services and physician is billing)
- No payment for “lost opportunity” (value of clinical practice time lost)
On-Call Arrangements

► Compensation Model Options
  ■ Fees paid per diem or per shift, regardless of whether called in
  ■ Episodic Fee: “activation” fees paid only if called in

► Red Flags Suggesting Risky Arrangement
  ■ Payment based on lost (clinical) opportunity
  ■ Double dipping (hospital pays for professional services when called in AND physician bills payors
  ■ Physician double booked
Twin Peaks Hospital System

Twin Peaks Hospital System has a number of agreements with physicians who refer patients to its hospitals

- Medical Directorships
- Clinic Coverage/Supervision Agreements
- Call Coverage Agreements
- Recruitment Agreements
- Management Services/Program Director Agreements
Twin Peaks Hospital System (cont’d)

► What Could Go Wrong:

- Agreements signed after services start/backdated
- $$ modified but contracts not amended to reflect changes
- Expired agreements not renewed
- Overlapping duties/ high number of hours
- FMV fails to include all compensation
Twin Peaks Hospital System (cont’d)

What Could Go Wrong: (cont’d)

- No time sheets to confirm services provided
- Agreements with flat fee compensation but no schedule or expected # of hours – cannot determine whether FMV
- Payments in excess of maximum $$ under the agreement
- Handwritten, unsigned modifications to agreements
- Oral agreements – physician performs work but hospital cannot pay without violating the law
Twin Peaks Hospital System (cont’d)

Twin Peaks Hospital System =
This could be any hospital or system… including yours!
Overview

- Hospital engages physician or a physician-owned entity to provide management services for component of its inpatient or outpatient services, such as a service line (e.g., cardiac, orthopedic)

- Hospital and physicians collaborate by having physicians manage (or co-manage along with hospital) a service line (e.g., cardiology, op surgery site)
Service Line/Co-Management (cont’d)

Overview (cont’d)

- Management company contracts with hospital to manage service line
- Goal is to further integrate and engage physicians in managing hospital service line
- Agreement can be with one or more physicians, medical practices, or a joint venture company owned jointly by physicians and a hospital
Service Line/Co-Management (cont’d)

Overview (cont’d)

- Typically includes a fixed, annual base fee for ongoing management and oversight AND a bonus fee for achievement of preset goals or outcomes (e.g., patient satisfaction, on-time surgery starts, following protocols, clinical improvement)

- Base fee often 50-80% of total using hours worked

- Bonus fee 20-50% of total tied to meeting pre-set goals
Service Line /Co-Management

► Typical Management Duties

■ Develop service line
■ Medical Director services
■ Budgeting
■ Strategic and business planning
■ Community relations
■ Patient, physician and staff satisfaction surveys
Service Line/Co-Management (cont’d)

Typical Management Duties (cont’d)

- Develop clinical protocols
- Develop objective, reasonable performance goals and benchmarks
- Staffing and workflow assessment
- Patient scheduling improvements (e.g., on-time surgery starts)
- HR management
Service Line / Co-Management (cont’d)

► Typical Management Duties (cont’d)

- Material management
- Medical staff relations/credentialing assistance
Management/Co-Management Agreements

Legal Considerations

- Stark
- Anti-kickback statute
- Tax exempt status
- Gainsharing civil monetary penalties law
- False Claims Act
- Bond financed space Rev Rule (97-13)
- Provider-based status
Management/Co-Management Agreements (cont’d)

► Management Services Agreement compliance with Anti-kickback safe harbor and Stark exception for personal services

■ Document justification for engaging physicians to manage (e.g., clinical improvement, quality, productivity)

■ Selection of physicians to manage (e.g., all on staff in specialty vs. big referrals only)

■ Include detailed description of specific services to be performed by physicians and require documentation of services

■ Management fee FMV and “set in advance” if possible and does not take into account referrals

■ FMV appraisal of management fee negates inference of improper interest

■ Term of one year and no renegotiation during first year
Management/Co-Management Agreements (cont’d)

► Even if management fee is FMV, it will not meet Anti-kickback statute personal services safe harbor if “aggregate compensation” is not “set in advance”

■ Typically, base fee set in advance and total, maximum opportunity for bonus fee stated

■ But bonus fee potential fails “set in advance” if it is “at risk”

■ OIG views percentage fees not “set in advance” under Anti-kickback statute

■ Inherent risk because co-management is always with referring physicians
Management/Co-Management Agreements (cont’d)

► Consider performance-based/incentive-based compensation carefully

■ Make sure metrics (patient satisfaction targets, on-time surgery starts) not too easy (no gimmes) and are reset at least every 2 years

■ Will not comply with Anti-kickback personal services safe harbor because not “set in advance”

■ Avoid any incentives that could induce limits on or reduction in Medicare or Medicaid services in violation of Gainsharing CMP Law, 42 USC § 1320a-7a(b)

■ Avoid volume based/revenue based performance measures (e.g., rewards for increased utilization, revenue, profit, change in case mix)
Stark Indirect Compensation Exception
(42 CFR 411.357(p); 411.354(c))

► If contract with joint venture use Stark “indirect” analysis – no Stark exception needed if aggregate compensation to referring physician does not vary with or reflect volume or value of DHS referrals

► Exception protects compensation under an “indirect compensation arrangement” if:
  ■ Compensation is FMV for items or services actually provided and is not determined in a manner that takes into account the volume or value of referrals or other business generated by the physician for the DHS entity
  ■ Arrangement is set out in writing signed by the parties and specifying the services
  ■ Arrangement does not violate the anti-kickback statute or any federal or state law governing billing
Gainsharing CMP Law
(42 USC 1320a-7(b)(1) and (2))

- Prohibits hospitals (or CAH) from knowingly making payments, directly or indirectly, to a physician to induce a physician to reduce or limit services to Medicare/Medicaid beneficiaries under the physician’s direct care
- Applies to all reductions in services (even if services not medically necessary)
- Implicated by quality and efficiency benchmarks that could be viewed as reducing services (clinical protocols, product standardization, cost savings)
Gainsharing CMP

- Cannot give incentives to reduce services or care
- Cannot reward changes in volume or case mix (steering/lemon dropping)
- Must maintain and measure quality and case mix
- Disclose to patients
- Hospitals can be liable for civil penalties of up to $2,000 per patient
- Hospitals can be excluded from Medicare/Medicaid for violation
General Concerns Under Fraud and Abuse/Gainsharing Laws

► Financial influence on physician referrals
► Financial impact on clinical decision making
► Overutilization (provide more services)
► Stinting on care (limit appropriate services)
► Cherry-picking (picking healthier patients)
► Lemon-dropping (drop sicker patients)
► Steering/Swapping (directing or cross-referrals based on financial arrangements)
The Bottom Line

► Be vigilant with physician alignment contracts
  ■ These laws have serious consequences
  ■ Both simple mistakes (expired or unsigned contracts) and more complex issues (such as FMV, commercial reasonableness) can have huge consequences

► Educate staff who deal with contracting and payments to prevent issues

► Create a culture of compliance (disclosure, non-retaliation) so you learn about a potential problem before the government does
A Compliant Physician Contract Review Process Helps

- Board Committee comprised of Board members and corporate officers
- Approves compensation and contract parameters/templates on annual basis
- Reviews and approves individual contracts if outside contract parameters/templates
- Committee members must be free of conflict of interest
- Follow IRS “rebuttable presumption” for physician contracts with “disqualified persons”

**Example**

- Delegates authority to review physician compensation to Board committee

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**Hospital Board**

**Physician Compensation Review Committee**

- “Rebuttable Presumption”
  - Approve in advance
  - Receive and rely on appropriate comparability data
  - Document the decision
QUESTIONS?

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