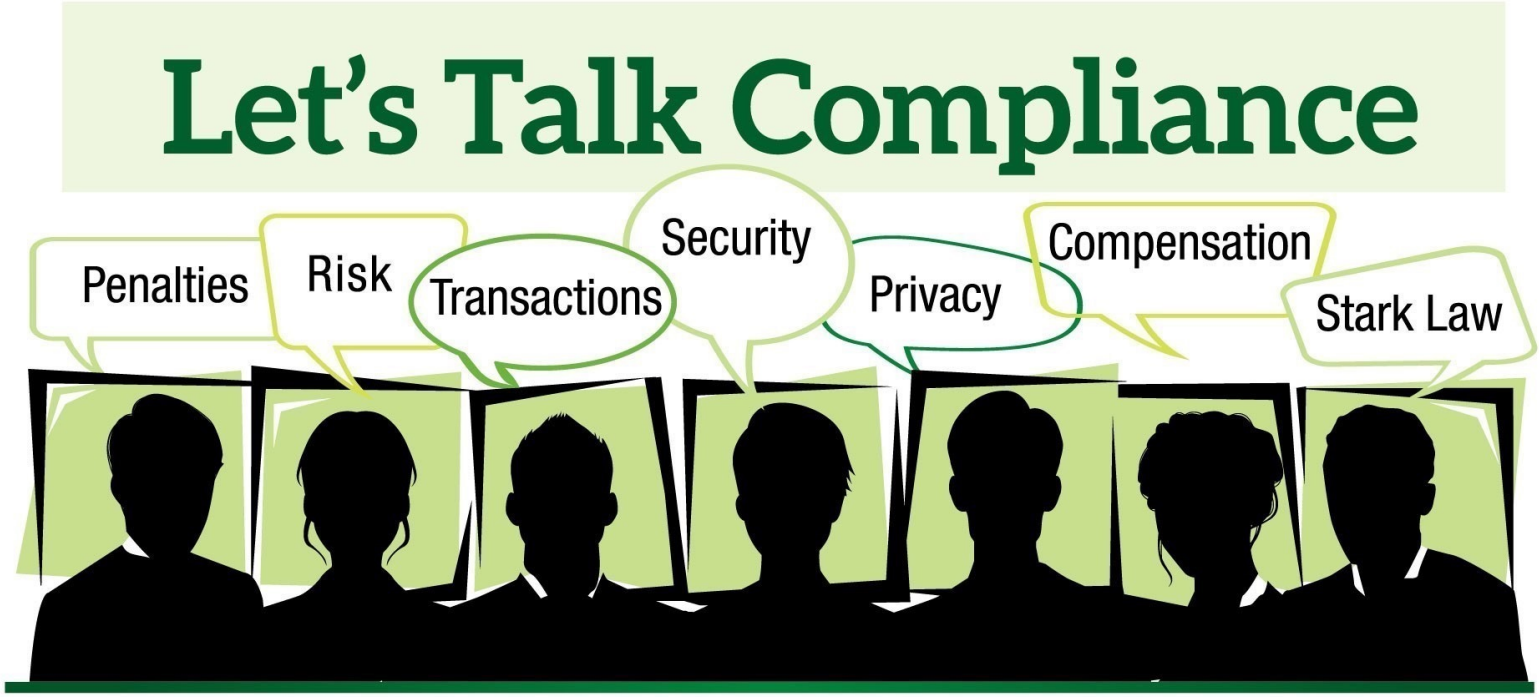
Stark Law Changes and Impact on Physician Compensation – Part 2



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Jana's practice focuses on healthcare regulatory issues, including fraud and abuse issues such as anti-kickback and self-referral law compliance; enrollment, coverage and payment issues; licensure issues; and health regulatory due diligence and risks related to acquisitions of health care companies.

Jana has worked with the spectrum of health care entities from academic medical centers (AMCs) to device and pharmaceutical manufacturers. She currently works with health systems, community hospitals, large physician groups, physician and midlevel management and staffing companies, DME suppliers, imaging companies, device manufacturers and distributors, as well as investors in health care entities. Jana is a member of the Health Care Industry Team and the Government Enforcement Defense & Investigations Practice.

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Angie consults with physician practices and healthcare systems in the areas of fair market value compensation; commercial reasonableness; physician compensation design, development, and strategy; physician/hospital alignment models; and value-based compensation. She assists physician practices and healthcare systems with strategic, financial, and operational issues. Angie serves as managing principal of PYA's Tampa office.

An author and frequent speaker, Angie has presented in live, webinar, and roundtable/panel settings for various organizations, including the American College of Healthcare Executives, Association of Corporate Counsel, Association of Healthcare Internal Auditors, American Health Law Association, Health Care Compliance Association, American Association of Provider Compensation Professionals, and various state hospital associations and societies of Certified Public Accountants.

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Roadmap of Presentation

- Federal Physician Self-Referral Law (a/k/a the “Stark Law”)
  - Background - Strict Liability Fraud and Abuse Statute, Exceptions and Penalties
  - “Fair Market Value”
  - “Commercially Reasonable”
  - “Indirect Compensation Arrangement”
- Changing Landscape of Physician Compensation
- Examples

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Federal Physician Self-Referral Law/Stark Law

- Prohibition:

  The Stark Law provides that "a physician who has a direct or indirect financial relationship with [a Designated Health Service or 'DHS'] entity, or who has an immediate family member who has a direct or indirect financial relationship with the DHS entity, may not make a referral for the furnishing of a DHS for which payment otherwise may be made under Medicare," *unless an exception applies.*

- Further, an entity that furnishes DHS pursuant to a prohibited referral may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral, *unless an exception applies.*

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Stark Law Overview

- Civil statute
- Strict liability (intent is irrelevant)
- Covers relationships with **physicians** (and physicians' immediate family members)
- If Stark is implicated, an exception must be met.

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Stark Law Overview

- Potential penalties
  - Payment denial/recoupment by Medicare and Medicaid
  - Civil monetary penalties up to $15,000 per prohibited service/billing ($26,125 for 2021)*
  - Circumvention schemes face civil monetary penalties of up to $100,000 per incident ($174,172 for 2021)*
  - Exclusion from Medicare/Medicaid participation
  - Liability under the False Claims Act

*Based on Federal Register (11/15/2021)

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“Financial Relationship” under the Stark Law

- “Financial relationship” means –

(i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or

(ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS. (42 CFR § 411.354(a)(1))

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Direct or Indirect Financial Relationship

- Types of financial relationships.

(i) A direct financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities between the entity furnishing DHS and the referring physician (or a member of his or her immediate family).

(ii) An indirect financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section. (42 CFR § 411.354(a)(2))

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“Compensation Arrangement” and “Remuneration”

- Compensation arrangement. A compensation arrangement is any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity. (42 CFR § 411.354(c))
- Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly. (Id. § 411.351)

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Compensation Exceptions

42 CFR § 411.357(c) - Bona fide employment relationships. Any amount paid by an employer to a physician (or immediate family member) who has a bona fide employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is –

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in any manner that takes into account the volume or value of referrals by the referring physician.

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Compensation Exceptions

42 CFR § 411.357(c) - Bona fide employment relationships. (*continued*)

(3) The remuneration is provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(5) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4).

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Compensation Exceptions (*continued*)

42 CFR § 411.357(d) - Personal service arrangements -

(1) General. Remuneration from an entity under an arrangement or multiple arrangements to a physician or his or her immediate family member, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:

(i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

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Compensation Exceptions (*continued*)

42 CFR § 411.357(d) - Personal service arrangements - (*continued*)

(ii) Except for services provided under an arrangement that satisfies all of the conditions of paragraph (z) of this section, the arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference **or** if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of contracts. A physician or family member may "furnish" services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or through locum tenens physicians (as defined at § 411.351, except that the regular physician need not be a member of a group practice).

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Compensation Exceptions (*continued*)

42 CFR § 411.357(d) - Personal service arrangements - (*continued*)

(iii) The aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

(iv) The duration of each arrangement is at least 1 year. To meet this requirement, if an arrangement is terminated with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original arrangement.

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Compensation Exceptions (*continued*)

42 CFR § 411.357(d) - Personal service arrangements - (*continued*)

(v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at § 411.351), is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(vi) The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.

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Compensation/Ownership Exception

42 CFR § 411.355(b) In-office Ancillary Services Exception. Services (including certain items of durable medical equipment (DME), as defined in paragraph (b)(4) of this section, and infusion pumps that are DME (including external ambulatory infusion pumps), but excluding all other DME and parenteral and enteral nutrients, equipment, and supplies (such as infusion pumps used for PEN)), that meet the following conditions:

(1) **Individual who furnishes the service**. They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) An individual who is supervised by the referring physician or, if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the services.

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Compensation/Ownership Exception

42 CFR § 411.355(b) In-office Ancillary Services Exception *(continued)*

…(2) **Location where service is furnished.** They are furnished in one of the following locations:

(i) The **same building** (as defined at § 411.351), but not necessarily in the same space or part of the building, in which all of the conditions of paragraph (b)(2)(i)(A), (b)(2)(i)(B), or (b)(2)(i)(C) of this section are satisfied:

(A) (1) The referring physician or his or her group practice (if any) has an office that is normally open to the physician's or group's patients for medical services at least 35 hours per week; **and**

(2) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 30 hours per week. The 30 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; **or**

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Compensation/Ownership Exception

42 CFR § 411.355(b) In-office Ancillary Services Exception *(continued)*

…(2) **Location where service is furnished.** They are furnished in one of the following locations:

(i) The **same building** (as defined at § 411.351), but not necessarily in the same space or part of the building, in which all of the conditions of paragraph (b)(2)(i)(A), (b)(2)(i)(B), or (b)(2)(i)(C) of this section are satisfied:

…(B) (1) The patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice (if any);

(2) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; **and**

(3) The referring physician regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; **or**

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Compensation/Ownership Exception

42 CFR § 411.355(b) In-office Ancillary Services Exception (*continued*)

…(2) **Location where service is furnished.** They are furnished in one of the following locations:

(i) The **same building** (as defined at § 411.351), but not necessarily in the same space or part of the building, in which all of the conditions of paragraph (b)(2)(i)(A), (b)(2)(i)(B), or (b)(2)(i)(C) of this section are satisfied:

…(C) (1) The referring physician is present and orders the DHS during a patient visit on the premises as set forth in paragraph (b)(2)(i)(C)(2) of this section or the referring physician or a member of the referring physician's group practice (if any) is present while the DHS is furnished during occupancy of the premises as set forth in paragraph (b)(2)(i)(C)(2) of this section;

(2) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; **and**

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Compensation/Ownership Exception

42 CFR § 411.355(b) In-office Ancillary Services Exception (*continued*)

…(2) **Location where service is furnished.** They are furnished in one of the following locations:

…(ii) A **centralized building** (as defined at § 411.351) that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services.

(iii) A **centralized building** (as defined at § 411.351) that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).

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Compensation/Ownership Exception

42 CFR § 411.355(b) In-office Ancillary Services Exception *(continued)*

…(3) **Billing of the service.** They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) The group practice if the supervising physician is a "physician in the group practice" (as defined at § 411.351) under a billing number assigned to the group practice.

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Compensation/Ownership Exception

42 CFR § 411.355(b) In-office Ancillary Services Exception (*continued*)

(3) **Billing of the service.** They are billed by one of the following:

…(iv) An entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice.

(v) An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs (b)(3)(i) through (iv) of this section under a billing number assigned to the physician, group practice, or entity, provided that the billing arrangement meets the requirements of § 424.80(b)(5) of this chapter. For purposes of this paragraph (b)(3), a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

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"Fair Market Value"

- CMS distinguished the meaning of "fair market value" for "general" purposes and for rentals.
  - In general, FMV means "[t]he value in an arm's-length transaction, consistent with the *general market value* of the subject transaction." (42 CFR § 411.351)
- CMS then refined the meaning of "general market value" for compensation, assets and rentals.
  - General market value means – "Compensation. With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties *that are not otherwise in a position to generate business for each other*."

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Fair Market Value Clarification

- *FMV* - In the December 2, 2020 Final Rule, CMS refused to make a safe harbor or rebuttable presumption for FMV based on a range of values in salary surveys – e.g., no presumption that salary at or below the 75th percentile is always appropriate and above the 75th is suspect.
  - Compensation should be based on the value of services without consideration of the business that the parties may generate for one another.

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Commercially Reasonable

- *CR* was defined in the December 2, 2020 Final Rule to mean that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty.
  - CMS also recognized that arrangements that result in losses can still be CR. "Examples of reasons why parties would enter into such transactions include community need, timely access to health care services, fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act (EMTALA), the provision of charity care, and the improvement of quality and health outcomes." (85 Fed. Reg. at 77,531)
  - CMS also recognized that CR is not a valuation consideration.

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“Indirect Compensation Arrangements”

- Definition of “indirect compensation arrangement” (42 CFR 411.354(c)(2))
  1. Unbroken chain between referring physician (or member of his/her immediate family member (IFM)) and the entity furnishing DHS *and*
  2. (a) Aggregate compensation varies with volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS *and*

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"Indirect Compensation Arrangements"

- Definition of "indirect compensation arrangement" (42 CFR 411.354(c)(2)) (*continued*)

(2) (b) The amount of compensation that the physician (or IFM) receives **per individual unit** –

(i) is not FMV for items/services actually provided;

(ii) could increase as the number or value of the physician's referrals to the entity furnishing DHS increases, or could decrease as the number or value of the physician's referrals to the entity decreases;

(iii) could increase as the amount or value of the other business generated by the physician for the entity furnishing DHS increases, or could decrease as the amount or value of the other business generated by the physician for the entity furnishing DHS decreases; **or**

(iv) is payment for the lease of office space or equipment or for the use of premises or equipment *and*

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“Indirect Compensation Arrangements”

- Definition of “indirect compensation arrangement” (42 CFR 411.354(c)(2)) (*continued*)

3. The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or IFM) receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

The exceptions that can apply are at 42 CFR 411.355 or 411.357(p)(indirect compensation exception).

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Indirect Compensation Arrangements Exception

42 CFR § 411.357(p) Indirect compensation arrangements. Indirect compensation arrangements, as defined at § 411.354(c)(2), if all of the following conditions are satisfied:

(1) (i) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.

(ii) [Rental of office space/equipment provision]

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Indirect Compensation Arrangements Exception

42 CFR § 411.357(p) Indirect compensation arrangements. (*continued*)

…(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in writing, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(3) [Reserved]

(4) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the compensation arrangement described in § 411.354(c)(2)(ii) satisfies the conditions of § 411.354(d)(4).

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Personally Performed Services under the Stark Law

- CMS expressed that “[p]rogram integrity concerns arise when payment for items or services provided as the result of a physician's referrals or other business the physician generates, rather than the physician's own labor, is included in the calculation of compensation.” 86 Fed. Reg. at 65,346.
- Personally performed services are not considered other business generated by the referring physician (Phase II; 12-2-2020 Final Rule)
- In the 2022 MPFS comments, CMS addressed the meaning of “personally performed,” stating that commenters discussing incident to billing may be “conflating” Medicare billing conventions with physician self-referral policy, and CMS thought clarification was warranted. See 86 Fed. Reg. at 65,350.

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Personally Performed Services under the Stark Law

- For purposes of the definition of “referral” in section 411.351, CMS stated DHS is not “personally performed” by the referring physician if it is performed or provided by any other person, including, but not limited to the referring physician's employees, independent contractors, or group practice members.
- This includes DHS furnished incident to the referring physician's professional services. See 86 Fed. Reg. at 65,350 (citing 66 Fed. Reg. at 871-872; 69 Fed. Reg. at 16,063).
- We would note the same could be said of split/shared visits.

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Impact of Changes – FMV/CR/Indirect Comp

- Examples of how compensation has changed over time
  - wRVU prevalence
  - APP wRVUs
  - “Personally performed” services (incident to and split shared services)
  - Look at total compensation (not just clinical)
- Valuation examples

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New Rules for Split-Shared Visits - 2022

- **2022 Final Rule** revised definition of "substantive portion" to mean *more than half of the total time of the visit*.
  - The visit is billed under the provider who performs more than 50% of the total time counted for the visit
  - Applied to critical care only, with other hospital-based services to follow in 2023
- **2022 Final Rule** allowed alternatives during transition
  - Meet the level of one of the key components to support selecting the physician as opposed to the APP as the billing provider -
    - History, Exam, or Medical Decision Making (MDM)

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New Rules for Split-Shared Visits - 2023

- **2023 Proposed Rule**
  - Delayed implementation to hospital-based services other than critical care to 2024
  - Confirmed definition of substantive portion during the transition to mean meeting the level of one of the three key components (history, exam, or MDM) or more than 50% of the total time spent by the physician and APP performing the split-shared visit.
- Created inconsistency with the 2023 proposed E/M guideline changes, which removes concept of meeting the level of medically appropriate history and/or exam.

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What Does this Mean for Physician Compensation?

1. It is anticipated that many visits previously billed under the physician will now be billed under the APP. Less wRVUs will be attributed to the physician, which will cause lower compensation for physicians in a productivity-based model overall.
2. Even in situations where the visit is billed under the physician, the threshold is *half the time* - meaning up to ~49% of the effort relates to the work performed by the APP. *And vice versa.*
3. Regardless –
   - CMS recognizes not all of the work effort provided under the visit is performed by the physician.
     - Your physician compensation plan should also recognize this.
     - Productivity-based models may not be the best compensation structure for hospital-based settings
     - Billing compliance does not equate to compensation compliance.

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Example Analysis: Hospital-Based Physicians – 25% Impact

	A	B	C	D=B*25%	E=C*D	F	G=E-F
Specialty	Median Compensation (of 4 2020 National Surveys)	Median wRVUs (of 4 2020 National Surveys)	Reported Median Compensation per wRVU (of 4 2020 National Surveys)	APP Impact - 25% (wRVUs)	"Value" of APP Impact ($)	Estimated Value - APP Supervision Stipend	Difference (Remaining Amount Embedded in Productivity Compensation)
Hospitalist	$301,181	4,335	$70.53	1,084	$76,455	$12,000	$64,455
Critical Care/Intensivist	$416,656	4,555	$94.09	1,139	$107,169	$12,000	$95,169

This example is for illustrative purposes only and does not represent an opinion of fair market value compensation or determination of commercial reasonableness. Any such determinations would be based on organization-specific facts and circumstances not available or applied in this example.

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Example Analysis - Continued

	A	B	C	D=B*25%	G=E-F	H=A/(B-D)	I
Specialty	Median Compensation (of 4 2020 National Surveys)	Median wRVUs (of 4 2020 National Surveys)	Reported Median Compensation per wRVU (of 4 2020 National Surveys)	APP Impact - 25% (wRVUs)	Difference (Remaining Amount Embedded in Productivity Compensation)	Estimated Adjusted Compensation per wRVU	Estimated Adjusted Compensation per wRVU Benchmark
Hospitalist	$301,181	4,335	$70.53	1,084	$64,455	$92.64	>75th
Critical Care/Intensivist	$416,656	4,555	$94.09	1,139	$95,169	$121.97	<75th

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Example Analysis - Continued

	A	J	K=A+J	L=K/(B-D)	M
Specialty	Median Compensation (of 4 2020 National Surveys)	Admin Pay	Total Stacked Compensation	Estimated Stacked Adjusted Compensation per wRVU	Estimated Stacked Adjusted Compensation per wRVU Benchmark
Hospitalist	$301,181	$24,000	$325,181	$100.02	>75th
Critical Care/Intensivist	$416,656	$24,000	$440,656	$129.00	>75th

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What About Primary Care Specialties?

- Remember – concern does not apply to organizations meeting the group practice and in-office ancillary exception
- In primary care specialties, we are concerned with attributing services performed *incident-to* by the APP to the physician.
- The easiest way to eliminate this concern is to attribute wRVUs for your primary care physicians based on ***rendering provider wRVUs*** rather than *billing provider wRVUs*.
- If your primary care specialty physician uses an APP to assist with hospital-based services, our concern surrounding attributing the physician wRVUs for APP work effort apply.
  - An analysis should be performed to estimate the impact to the physician in this scenario.

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What are the Best Practices for APP Impact Estimation?

Consider the following for determining an estimate:

- Per physician or per specialty basis
  - Facts and circumstances specific
- Sample medical record review
- Observation/physician shadowing
- Physician schedule review
- Clinical staff interviews
- Time studies and CPT® code analysis of pre-, intra-, and post time

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Questions?

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Thank you!

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