Health Law Webinar

The Annual Regulatory Update

December 9, 2020

Fredrikson & BYRON, P.A.

Agenda

- Research during COVID-19.
- Stark and Antikickback.
- Medicare Physician Fee Schedule.
- Medicare Inpatient Prospective Payment.
- Miscellaneous Points.

Research in the Time of COVID-19

- Many “official” sources of information aren’t updated.
- Check the 4 Interim Final rules, and the CMS FAQs. Manuals generally have not been updated for COVID-19.
- Remember the legal hierarchy. Manuals are not binding. See 10/20 and 8/19 webinars at https://www.fredlaw.com/health_law_webinars/.

New Stark/Kickback Regs.

- Stark: 85 FR 77492, December 2, 2020 https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26140.pdf
- Antikickback: 85 FR 77684, December 2, 2020 https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf
- Both generally effective 1/19/21.

Stark vs. Antikickback

- You HAVE to meet a Stark exception. You do NOT have to meet antikickback safe harbor.
- Intent is irrelevant under Stark. Intent is EVERYTHING under an antikickback.
- Stark is civil. Antikickback is criminal.

People Often Don’t Get It

“One commenter requested that CMS address the differences between the documentation and signature requirements in the cybersecurity exception and OIG’s cybersecurity safe harbor. The commenter highlighted that the writing requirement in the exception requires that the arrangement is documented in writing but does not require a formal written agreement that is signed by the parties, whereas the corresponding requirement in the OIG’s proposed cybersecurity safe harbor requires that the arrangement is set forth in a written agreement that is signed by the parties and describes the technology and services being provided and the amount of the recipient’s contribution, if any (84 FR 55765).”

Page 77643

Stark Primer

- See our September 2018 Webinar.
- Understand the Designated Health Services (DHS).
- If a doctor orders a DHS provided by an entity, any comp to/from the entity must meet an exception.
- If there is an improper financial relationship, billing Medicare is prohibited. (The “period of disallowance”).

The Big Three

- Commercially reasonable.
- Compensation is not determined in any manner that takes into account the volume or value of referrals/other business.
- Compensation is at fair market value for items or services actually furnished.

The Subtlety of the Stark

For example, the exception at section 1877(e)(2) of the Act for bona fide employment relationships requires that the remuneration provided to the physician is pursuant to an arrangement that would be commercially reasonable (even if no referrals were made to the employer) The exception at section 1877(e)(3)(A) of the Act for personal service arrangements uses slightly different language to describe this general concept, and requires that the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

Page 77530

Prospective Perspective

“The policies finalized here are prospective only and represent CMS policy regarding the volume or value standard and other business generated standard going forward from the effective date of this final rule.”

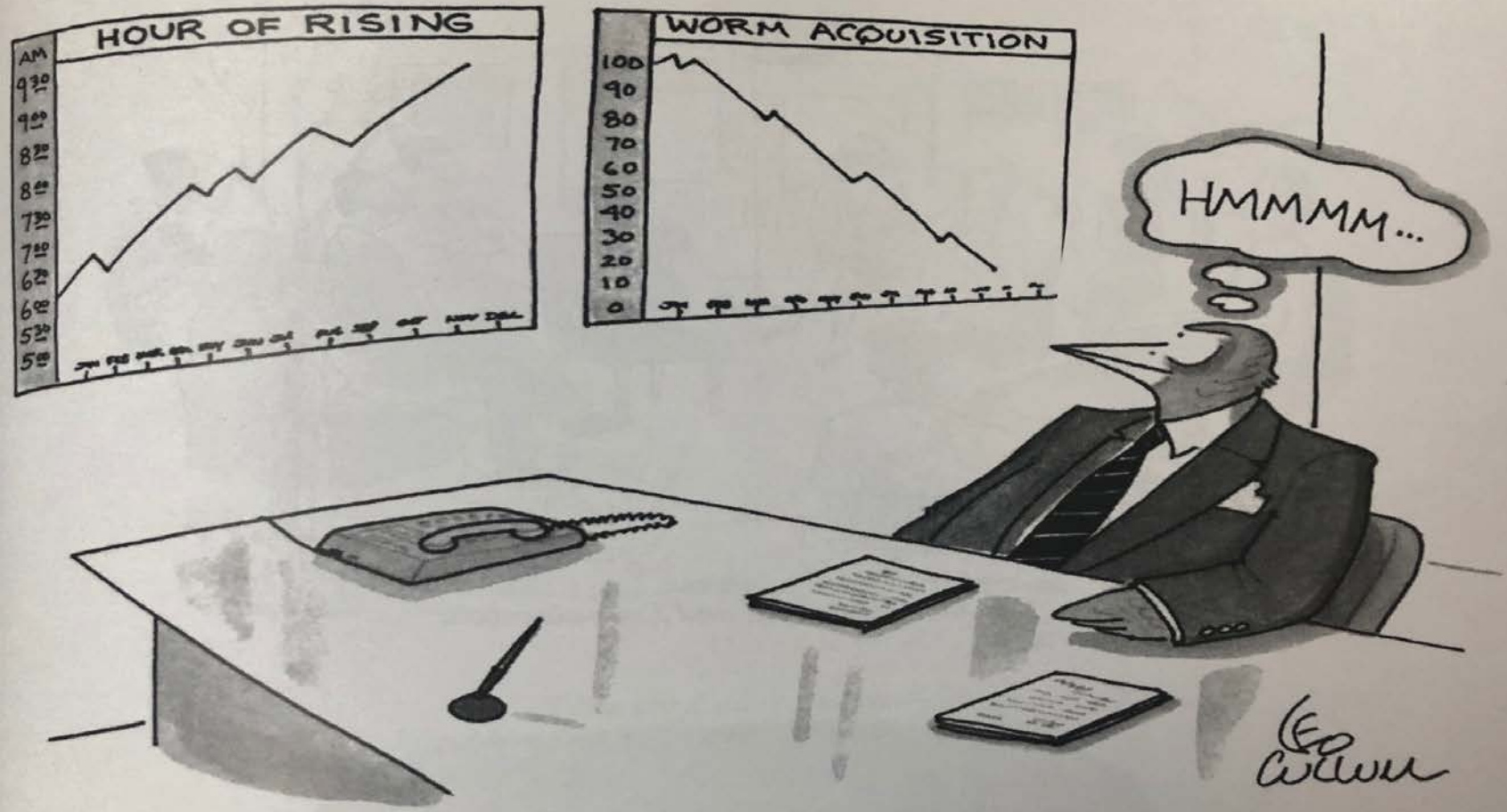
Page 77541

Changes: The Big Picture

- Substantial changes to definitions, including compensation related terms/general and fair-market value.
- New exceptions for value-based arrangements, donations of cybersecurity, and limited remuneration to a physician.
- Substantial changes to other exceptions.
- A tip of the chapeau?

Key Points About Definitions

- They apply only to Stark. The same word may have a different meaning in kickback, IRS or other governmental regulations.
- Some words are defined then used differently. *See* "entity" and "referral."
- Does anybody really know what a correlation is?


HOUR OF RISING
AM
WORM ACQUISITION
100
90
80
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60
50
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HMMMM...

Key Points About Definitions

- They apply only to Stark. The same word may have a different meaning in kickback, IRS or other governmental regulations.
- Some words are defined then used differently. *See* "entity" and "referral."
- Does anybody really know what a correlation is?
- Are they using "deem" correctly?

Deem, De-deem Deem?

“However, as we explained in the proposed rule, the special rule at current § 411.354(d)(1) is merely a deeming provision, not a requirement (84 FR 55814).”

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Limited Remuneration to a Physician

- Permits compensation up to $5,000 per calendar year, adjusted for inflation.
- Compensation can't take into account volume and value of referrals/other business, can't exceed FMV, must be commercially reasonable absent referrals and, if a lease, not per click.
- If remuneration is conditioned on referrals, must meet 411.354(d)(4).
- Applies to employees and locums physicians.

Limited Remuneration to a Physician

- Doesn’t require a writing!!
- Physician owners stand in the shoes of the group.
- The $5,000 is for ALL transactions, not PER transaction.

411.357(z)

Value-Based Payments

- Definition heavy.
- Differentiates based on the level of risk, full or meaningful downside but with a 3rd "value-based arrangement" option.
- Must be a "Value-based participant" in a "value-based enterprise."
- Up to 12 months before value-based arrangement.
- Some differences with antikickback. But so what?

411.357(aa)

Value-Based Enterprise (VBE)

Two or more VBE participants—

VBE Participant

A person or entity that engages in at least one value-based activity as part of a value-based enterprise.

Value-Based Enterprise (VBE)

Two or more VBE participants—

(1) Collaborating to achieve at least one value-based purpose;

(2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;

(3) That have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and

(4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

Value-Based Purpose

(1) Coordinating and managing the care of a target patient population;

(2) Improving the quality of care for a target patient population;

(3) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or

(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

Value-Based Activity

Any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

(1) The provision of an item or service;

(2) The taking of an action; or

(3) The refraining from taking an action.

Full Financial Risk

- Prospectively financially responsible for all care items and services.
- In essence, capitation.

Meaningful Downside Risk

- Physician is responsible to repay or forego no less than 10% of the total value of the remuneration.

“We’ll Just Carve Out Medicare”

- Not helpful. Any compensation triggers Stark.
- Remember the “carve out conundrum.” (Though that is really a kickback issue.)

Full Risk Exception

- Within 12 months, at full risk.
- Remuneration is for/from the value-based activity and targeted patients.
- Not an inducement to limit medically necessary items/services.
- Not conditioned on referral of non-participants.
- If required to refer participants, must be written, allow pt or ins. to opt out.
- Records kept 6 years.

Meaningful Downside Exception

- At risk for entire duration, with methodology set in advance, written.
- Remuneration for/from target population.
- Not inducement to limit medically necessary stuff.
- Same referral rules/record rules.

Value-Based Arrangements Exception

- Writing listing activity, process, target, methodology, outcome measure (if any!)
- Methodology set in advance.
- Remuneration for/from the activity.
- Commercially reasonable.
- Annually monitor bunch of stuff.
- The typical referral and other language.

Are These Protected?

- Pay physician to attend coordination of care meeting for discharge?
- Offer physician telehealth equipment, to keep seniors out of the hospital, with need to repay 10% if certain targets aren’t hit?
- Group is mad at you, and to curry favor you offer the above. Is the remuneration “for” the activity?

There is a lesson here:

“We decline to provide a list of items or services, actions, and ways to refrain from taking an action that qualify as value-based activities. We are concerned that even a non-exhaustive list of common value-based activities could unintentionally limit innovation and inhibit robust participation in value-based health care delivery and payment systems.”

Page 77500

And here?

"Specifically, some commenters asked whether particular items or services, such as transportation services or the provision of non-medical personnel, would qualify as value-based activities. Commenters did not explain how the arrangements for those particular items or services would implicate the physician self-referral law….We assume that the commenters were referring to the provision of transportation services to a beneficiary, which would not implicate the law unless the beneficiary was a physician or an immediate family member of a physician.

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Cybersecurity

- Non-monetary technology/software.
- Eligibility/amount not referral linked.
- Physician/practice don’t make it a condition of doing business.
- Agreement is written.

Isolated Financial Transactions

- One-time single payment (multiple installment payments if payment is fixed in advance).
- A one-time sale of property or practice, single instance of forgiveness of an amount in a bona fide dispute.
- Clarifies it won't cover a single payment for multiple or repeated services.

411.357(f)

Definitions

Fair Market Value

- “The value in an arms-length transaction, consistent with the general market value of the subject transaction.”
- Equipment: general commercial purposes (not taking into account its intended use) consistent with the general market value.
- Office space: the above, plus without adjustment to reflect additional value the perspective lessee would attribute to proximity or convenience.

General Market Value

- Asset: The price the asset would bring on the date of acquisition of the asset as a result of bonafide bargaining between a well-informed buyer and seller not otherwise in a position to generate business for each other.

General Market Value: Compensation/Rental of Equipment

- The compensation that would be paid at the time the parties enter into the service agreement as a result of bona fide bargaining between well informed parties not in a position to generate business.

Commercially Reasonable

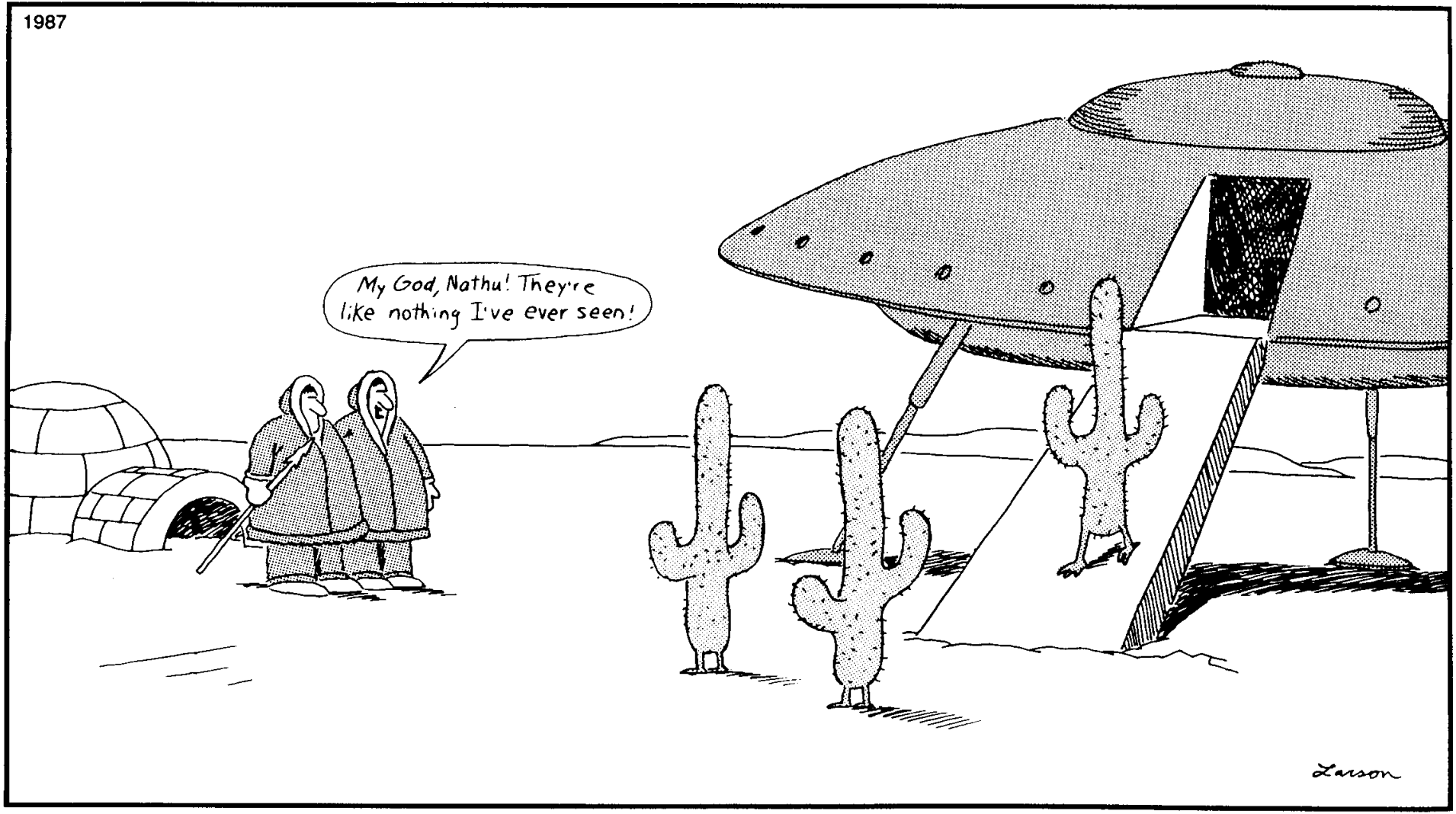
The particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties

What is Commercially Reasonable?

- Community need.
- Timely access to health care services.
- Fulfillment of licensure or regulatory obligations, including Intalla.
- The provision of charity care.
- Improvement of quality and health outcomes.
- “Makes sense as a means to accomplish the party’s goals.”

Page 77531

1987



Understanding the Framework of the Compensation Exceptions

- § 411.354 has section (c) discussing compensation arrangements, (d) setting out special rules on compensation, and (e) special rule on compensation arrangements.
- § 411.352(i) discusses special rules for productivity bonuses and profit shares in a group practice.
- Yes, that is confusing.

What is Compensation?

- Theft generally does not create a compensation arrangement.
- “We note that, if a physician pays an entity $10 in cash for a gift card worth $10, we do not believe that this would constitute a financial relationship for purposes of the physician self-referral law.”

Page 77605

What is Compensation?

"In each of the arrangements disclosed to the SRDP, the arrangement was determined by the disclosing party not to satisfy the requirements of the exception at § 411.357(e) solely because the physician practice that the recruited physician joined had not signed the writing evidencing the arrangement. We do not believe, however, that under the circumstances described by the parties disclosing to the SRDP, there exists a compensation arrangement between the physician practice and the hospital…of the type against which the statute is intended to protect; that is, the type of financial self-interest that impacts a physician's medical decision-making."

Page 77599

Compensation Formula Limits Change For Group Practices

- All DHS revenue for the group/subgroup must be aggregated.
- Subgroups must have at least five physicians.
- The same allocation methodology must be used for all DHS.
- This now applies to non-Medicare DHS revenue.
- Effective 1/1/22.

Productivity Bonuses

- Services personally performed or incident to if not directly related to volume on the value of referrals (may directly relate for incident to).
- Deemed not to relate to the volume or value if:
  - Personally performed by the physician.
  - Not DHS and not considered DHS if payable by Medicare.
  - Revenues from DHS are less than 5% of total revenue and each physician's compensation.

Correlation

“For purposes of applying this paragraph, a positive correlation between two variables exists when one variable decreases as the other variable decreases or one variable increases as the other variable increases.”

§ 411.354(d)(5)

Some Welcome Clarity

"To the extent that a productivity bonus (or portion of a productivity bonus) paid by a group practice to a physician in the group is solely based on services performed by a member of the physician's care team that are not designated health services, the productivity bonus (or portion of the productivity bonus) would not violate § 411.352."

Page 77566

Unit-Based Compensation

- Time or per click compensation is deemed not to take into account other business if:
  - At FMV.
  - Does not vary during the course of the compensation arrangement in a manner to take into account referrals or other business, including private pay, except services personally performed by the physician.

Takes into Account Volume/Value/ Other Business

"Compensation to a physician or immediate family member takes into account…if the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with…"

§ 411.354(d)(4)

Set in Advance

- Deemed to be set in advance if set out in writing before the furnishing of items/service/space & formula is set in sufficient detail it can be objectively verified.
- May be modified at any time if:
  - All requirements of an exception are met on the effective date.
  - The modified compensation formula is determined before the furnishing of the item/service and written in sufficient detail to permit objective verification.*

*The preamble notes there is no signature requirement.

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Set in Advance

"The surest and most straightforward way for a party to establish that the compensation under an arrangement is set in advance is to satisfy the deeming provision at § 411.354(d)(1)(i). Under [it], the parties document the compensation in writing prior to the furnishing of items, services, office space, or equipment in sufficient detail so that it can be verified are *deemed* to satisfy the set in advance requirement. However, we are reiterating in this final rule that the compensation (or other formula determining the compensation) does not need to be documented in writing and it does not need to be deemed to be set in advance under [this provision] in order to satisfy the set in advance requirement during the first 90 days of the arrangement."

Page 77595-96

New Flexibility?

"Given the writing requirement in the new rule at § 411.354(d)(1)(ii) on modifying compensation during the course of an arrangement, we are qualifying this statement in the final rule. As finalized in this rule, compensation may be set in advance even if it is not set out in writing before the furnishing of items or services as long as the compensation is not modified at any time during the period the parties seek to show the compensation was set in advance. For example, assume the parties to an arrangement agree on the rate of compensation before the furnishing of items or services, but do not reduce the compensation rate to writing at that point.

New Flexibility?

Assume further that the first payment under the arrangement is documented and that, under § 411.354(e)(4), during the 90-day period after the items or services are initially furnished, the parties compile sufficient documentation of the arrangement to satisfy the writing requirement of an applicable exception. Finally, assume that the written documentation compiled during the 90-day period provides for a rate of compensation that is consistent with the documented amount of the first payment, that is the rate of compensation was not modified during the 90-day period. Under these specific circumstances, we would consider the compensation to be set in advance. . . . To the extent that our preamble discussion in the CY 2016 PFS final rule suggested that the rate of compensation must always be set out in writing before the furnishing of items or services in order to meet the second advance requirement of an applicable exception, we are retracting that statement."

Page 77592

It is Not THAT Flexible!

- Imagine a $500 per shift call coverage agreement. On day 70, the parties agree to go to $600 per shift. The amendment may not be retroactive, and there must be sufficient writing before the first service is furnished. The parties have through day 90 to reduce the agreement to writing and obtain signatures, but modified compensation must be in writing.

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Fixing Mistakes

- 411.353(h) creates a new reconciliation principle. There is no prohibition on billing if, within 90 calendar days following termination of the compensation agreement, all discrepancies are reconciled and the arrangement otherwise meets an exception.

Period of Disallowance

- Deleted disallowance text in 411.353(c).
- “The general principle stated in the CY 2008 PFS proposed rule that the period of disallowance under the physician self-referral law should begin on the date when a financial relationship fails to satisfy all the requirements of any applicable exception and end on the date that the financial relationship ends or satisfies all the requirements of an applicable exception remains true”

Page 77581

Period of Disallowance

- Far more flexibility for errors discovered during the term than those discovered subsequently.
- Hesitation to allow “unringing the bell.”
- Rejected the idea of 90 days after the comp. Opted for “facts and circumstances.”
- Could there be a more compelling argument for auto-renew???

Page 77583

Period of Disallowance

- For nonmonetary compensation typically ends December 31 of the year in which the excess compensation is provided.
- But not if it's fancy? "For example, if a hospital gifts a physician an expensive new car on December 30 of the calendar year, the compensation arrangement that results from the transfer of the remuneration would not appropriately be considered to end the next day. Rather, the remuneration should be viewed as a likely exchange for the physician's future referrals."

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Stark is Black and White?

“If the payment discrepancy or failure to reconcile it (that is, recover excess compensation or collect compensation owed) is significant enough to give rise to a separate financial relationship, that financial relationship must satisfy the requirements of an applicable exception once it exists. The commencement date of the second financial relationship depends on the facts and circumstances, such as the amount of excess compensation or unpaid compensation and how long the known overpayment or underpayment of the compensation has continued. For example, a large amount of excess compensation that is not recovered may give rise to a financial relationship in a shorter amount of time than a very small amount of unrecovered excess compensation or unpaid compensation. Thus, even if the entity is deemed not to have violated the physician self-referral law’s billing prohibition once the original compensation arrangement is ultimately reconciled, the entity would be prohibited from submitting a claim or bill for a designated health service referred by the physician beginning at the point where the second financial relationship exists.”

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New Burden of Proof

- “The ultimate burden of proof (burden of persuasion) at each level of appeal is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral (and not on CMS or its contractors to establish that the service was furnished pursuant to a prohibited referral).”
- Burden of production is on claimant but may shift depending on the evidence.

§ 411.353(c)(2)

§ 411.354(e) is Important

- “Writing” can be satisfied by a collection of documents, including contemporaneous documents.
- Signature requirement can be satisfied by an electronic or other signature valid under Federal **OR** State law.
- (4) explains signatures obtained within 90 days are adequate.

What Constitutes Evidence?

- Informal communication via email or text.
- Internal notes to file.
- Similar payments between the parties from prior arrangements.
- Generally applicable schedules.
- Other documents recording similar payments to or from other similarly situated physicians for similar services.

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Direct Referrals

- Whether employment, personal services, or managed care, the compensation must:
  - Be set in advance for the duration of the arrangement, with changes prospective.
  - Consistent with FMV.
  - Meets a regulatory exception in .355 or .357.
  - Referral requirement is in writing and signed.
  - Patient or patient's insurer may choose another option.

Direct Referrals

- Whether employment, personal services, or managed care, the compensation must (continued):
  - Required referrals relate solely to the arrangement and are reasonably necessary for a legitimate business purpose.
  - Neither the existence of the arrangement nor the compensation is contingent on the number or value of referrals, though it may require the physician to refer an established percentage or ratio of patients.

Exclusive Use

- Clarifies exclusive use only prohibits use by the lessor.
- Other lessees or sublessees may use the space.

Assistance to Compensate Non-Physician Practitioners*

- Must commence before physician enters agreement.
- Clarifies that if a nurse becomes a nurse practitioner, the NP can still qualify.
- Still limits compensation to 50% of compensation and benefits paid to the non-physician practitioner during the first two years and other provisions.

*They really mean “recruit.”

411.357(x)

What Exception Can I Use?

- A perennial question. Must you use the exception that that has the right “chapeau?”
- Can a lease fit in FMV? How about an honorarium???

FMV Exception is Broad

"We note that, as amended in this final rule, the exception for fair market value compensation at § 411.357(l) may be used for office space and equipment lease arrangements. The exception for fair market value does not include an exclusive use requirement."

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You Can Always Use FMV

"In Phase I, we finalized § 411.357(l), stating that parties could use the exception, even if another exception potentially applied to an arrangement (66 FR 919). We explained our belief that the safeguards incorporated into the exception for fair market value compensation were sufficient to cover various compensation arrangements, including arrangements covered by other exceptions. In Phase II…we declined to extend [the FMV exception] to arrangements for the rental of office space and emphasized that [the FMV exception] applied only to payments *from* an entity *to* a physician for items and services…We have reconsidered our policy regarding the application of [the FMV exception] through our administration of the SRDP, we have seen legitimate non-abusive arrangements for the rental of office space but could not satisfy the requirements of [a lease exception] because the term of the arrangement was less than one year…to provide flexibility to stakeholders…we are now finalizing modifications…to permit parties to rely on the exception for fair market value."

Page 77605

But Did They Really Mean That?

"We continue to believe that the exception for payments by a physician at Section 1877(e)(8) of the Act was not meant to apply to compensation arrangements that are specifically excepted by other *statutory* exceptions in Section 1877 of the Act. Given the placement of the exception for payments by a physician as the final statutory exception at Section 1877(e) of the Act, we believe that this exception functions as a catch-all to protect certain legitimate arrangements that are not covered by the exceptions at Sections 1877(e)(1)-(7) of the Act."

Page 77604

Incidental Medical Staff Benefits

- “Web site” is now “website.”
- Currently cap $423 per calendar year / $36 an episode.

HHS Memo: Impact of *Allina* on Medicare Payment Rules

- Released October 31, 2019
- Explains how CMS should apply the *Allina* ruling to its enforcement actions.

HHS Memo: Impact of *Allina* on Medicare Payment Rules

- "Where a statute or regulation is drafted narrowly enough to create the relevant program norm, the agency can provide additional clarity through guidance without creating a new non-statutory or non-regulatory norm."
- "Conversely, to the extent that IOMs and similar guidance set forth payment rules that are not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance in enforcement actions, because under *Allina*, it was not validly issued.

HHS Memo: Impact of *Allina* on Medicare Payment Rules

- "We do not interpret *Allina* as compelling CMS's contractors to promulgate [LCDs] using notice-and-comment rulemaking. . . . But as a result of *Allina*, government enforcement actions based solely on LCDs are generally unsupportable."

2021 Medicare Physician Fee Schedule

Revaluing RVUs

- The credit physicians get for services will change.
- Comp. systems that pay based on RVUs will need to be reevaluated. If not, pay will change without changes in the amount of work done.

2021 Medicare Telehealth List

- Some permanent additions (Category 1).
- Some temporary additions (Category 3).
- Temporary telehealth additions (Category 3) permitted through 12/31/21 or the calendar year in which the public health emergency (PHE) ends, whichever is later.
- See Table 16 in the Final Rule.

Permanent Telehealth Additions

- Care Planning for Patients with Cognitive Impairment 99483;
- Domiciliary, Rest Home, or Custodial Care Services 99334 and 99335;
- Group Psychotherapy 90853;
- Home Visits 99347 and 99348;
- Neurobehavioral Status Exam 96121;
- Visit Complexity Inherent to Office/Outpatient E/M for Ongoing Care Related to Serious or Complex Condition G2211; and
- Prolonged Office/Outpatient Service E/M G2211.

Temporary Telehealth Additions (Category 3)

(Green indicates that the code is in addition to the list of codes in the proposed rule.)

- Domiciliary, Rest Home, or Custodial Care Services, Established Patients 99336 and 99337;
- ED Visits 99281, 99282, 99283, 99284 and 99285;
- Home Visits, Established Patient 99349 and 99350;
- Nursing Facilities Discharge Day Management 99315 and 99316;

Temporary Telehealth Additions (Category 3)

- Psychological and Neuropsychological Testing 96121, 96130, 96131, 96132, 96133, 96136-9;
- Therapy Services, Physical and Occupational (and Speech) Therapy, All Levels 97161-68, 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521-4, 92507;
- End-Stage Renal Disease Monthly Capitation Payment Services 90952, 90953, 90956, 90959, and 90962;
- Subsequent Observation and Observation Discharge Day Management 99217, 99224, 99225, and 99226;

Temporary Telehealth Additions (Category 3)

- Initial Hospital Care and Hospital Discharge Day Management 99221, 99222, 99223, 99238, 99239;
- Critical Care Services 99291, 99292;
- Inpatient Neonatal and Pediatric Critical Care, Subsequent 99469, 99472, and 99476; and
- Continuing Neonatal Intensive Care Services 99478-80.

Geographic and Site of Service Limitations

- Coronavirus Preparedness and Response and Families First Acts allowed CMS to waive geographic, site of service, and practitioner restrictions on telehealth.
- CMS previously said (via fact sheet and press release) that such waivers would end at conclusion of PHE.
- Now, per the final rule, CMS says the geographic, site of service, and practitioner waivers will through 12/31/21 or the calendar year in which the PHE ends, whichever is later.

Telehealth in Nursing Facilities

- Effective 1/1/2021, practitioners may conduct a telehealth visit for subsequent nursing facility care services once every 14 days (instead of once every 30 days).

Communication Technology-Based Services (CTBS)

- CTBS = brief non-face-to-face, technology-based services.
  - E-visits (G2061-63);
  - Remote evaluation of pre-recorded video/images (store and forward) (G2010); and
  - Virtual check-ins (G2012).

Communication Technology-Based Services (CTBS)

- Effective 1/1/2021,qualified non-physician practitioners (NPPs), such as licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists, and speech language pathologists may bill for all CTBS (i.e., e-visits, remote evaluation of pre-recorded video and images, and virtual check-ins).

Communication Technology-Based Services (CTBS)

- E-visits, formerly G2061-63, are now 98970-72.
- Remote evaluation of pre-recorded video/images (store and forward) is G2250, and virtual check-ins are G2251, for practitioners who cannot independently bill for E/M services.
  - Therapy modifier for private practice PT, OT, or SLP.

Communication Technology-Based Services (CTBS)

- The patient consent for CTBS (to notify the patient of the co-pay/cost sharing) may be documented by auxiliary staff under general supervision, and the timing and matter of patient consent “should not interfere with the provision of one of these services.”
- Remember that virtual check-ins and e-visits are not allowed for new patients after the end of the PHE.

Extended Audio-Only Visits

- Audio-only telehealth codes currently approved under Section 1135 PHE waivers may only be used during the PHE.
- However, CMS created a new code—G2252—for extended services delivered via synchronous communications technology, including audio-only (e.g., virtual check-ins).
  - Cross-walked to 99442, making it reimbursed higher than current limited duration virtual check-in code.
  - Intended for when acuity of patient problem does not warrant an in-person visit but more time is required to make the assessment.
  - Considered a CTBS.
  - **New code may be used through 2021.**

Direct Supervision

- Until 12/31/21 or the calendar year in which the PHE ends, whichever is later, “direct supervision” may be provided using real-time, interactive audio-visual technology.
  - This clarifies that services may be provided incident-to a distant-site practitioner’s services under the direct supervision of the billing practitioner via virtual presence.

Supervision of Diagnostic Tests by Certain NPPs

- Effective 1/1/21, nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs), certified nurse midwives (CNMs), and certified registered nurse anesthetists (CRNAs) may supervise diagnostic tests within their scope of practice and as permitted by state law.

Other Scope of Practice & Related Issues

- “Incident to” services by a pharmacist.
- Therapy assistants furnishing maintenance therapy.
- Medical record documentation.

Teaching Physicians

- Permanent changes allowing virtual presence by teaching physician in rural settings (outside an MSA).
  - Changes to 42 CFR § 415.172, 415.174, 415.180 and 415.184.
- Does NOT include surgical, high risk, interventional or other complex procedures, services performed through an endoscope or anesthesia services.

Teaching Physicians

- Expanded lower and mid-level E/M services provided by a resident at rural teaching hospitals under the primary care exception to include:
  - CPT codes 99421-99423, and 99452
  - HCPCS codes G2010 and G2012.

Meaning of “Audio/Visual”

- What does “audio slash visual” mean?
- Audio OR visual? Audio AND visual?
- Remember Slash the guitarist.

Moonlighting Residents

- Extending policy during COVID-19 allowing certain services of residents provided to inpatients to be separately payable.
  - § 415.208(b)(2)
- This change is NOT limited to rural settings.
- Documentation required to avoid duplicate payment.

Remote Physiologic Monitoring Services (RPM)

- Clarification of payment policies for CPT codes 99453, 99454, 99091, 99457, and 99458
  - Appropriate for chronic and acute conditions.
  - Only physicians and NPPs who are eligible to furnish E/M services may bill RPM services.
  - Auxiliary personnel (including contacted employees) may provide incident to services under 99453 and 99454.
  - Consent form patients can be obtained at the time that RPM services are furnished.

RPM

- Definitions:
  - “Interactive communication” = real-time, synchronous, two-way interactions that can be enhanced with video or other kinds of data (see HCPCS code G2012).
  - Medical Device: FFDCA definition, must transmit reliable and valid data electronically/automatically.
- Post-COVID-19 PHE:
  - 16 days of data each 30 days (99453, 99454).
  - Must have an established patient-physician relationship.

Clinical Laboratory Fee Schedule

- Updates per CARES Act and Further Consolidated Appropriations Act, 2020:
  - Next data reporting period: January 1, 2022 – March 31, 2022, for CDLTs that are not ADLTs (based on the data collection period of January 1, 2019 – June 30, 2019).
    - Thereafter, three-year data reporting cycles for CDLTs that are not ADLTs (2025, 2028, and so on).
  - 0.0 percent payment reduction for CY 2021
  - CYs 2022-2024, payment may not be reduced by more than 15% year over year.

Home Infusion Therapy Notifications

- Prior to the furnishing of home infusion therapy to an individual, a physician must provide notification of available options (e.g., home, physician's office, HOPD).
- Discuss options available for furnishing infusion therapy under Part B and annotate such discussion in the patient’s medical records prior to establishing a home infusion therapy plan of care.

Electronic Prescribing of Controlled Substances

- Finalizes use of the National Council for Prescription Drug Programs, (NCPDP) SCRIPT 2017071 standard for electronic prescribing of controlled substances.
- Effective date of January 1, 2021.
- Compliance date of January 1, 2022.
- Exceptions to be outlined in future rulemaking.

Medicare Diabetes Prevention Program (MDPP)

- Revised MDPP policies for current PHE (effective Jan. 1, 2021) and any future 1135 waiver event.
  - Flexible options for adjusting and resuming services.
  - Suppliers may deliver MDPP services virtually or suspend in-person MDPP services.
  - MDPP beneficiaries may continue services virtually, even after the PHE or 1135 waiver event has concluded.
  - Weight loss requirements for ongoing eligibility will resume for new participants starting Jan. 1, 2021.

OUD Treatment Services Furnished by OTPs

- Expanded to include opioid antagonist medications, including naloxone.
- OTP must make a good faith effort to ensure no duplicative payments for naloxone.
- Periodic assessments may be furnished via two-way interactive audio-video communication technology, as clinically appropriate.

Changes to IPPE and AWV

- Must include a review of any current opioid prescriptions, screening for potential SUD, and a referral for treatment as appropriate.
  - Changes to § 410.15 and 410.16.

Elimination of NCDs

- Discuss explains operation of NCDs.
- Eliminates 6 NCDs:
  - NCD 20.5 Extracorporeal Immunoadsorption (ECI) Using Protein A Columns
  - NCD 30.4 Electrosleep Therapy
  - NCD 100.9 Implantation of Gastrointestinal Reflux Devices
  - NCD 110.19 Abarelix for Treatment of Prostate Cancer*
  - NCD 220.2.1 Magnetic Resonance Spectroscopy
  - NCD 220.6.16 FDG PET for Inflammation and Infection.

  * They left this one out, but it SEEMS like it is deleted.

PREP Act Declaration Amendment

- Fourth amendment announced December 3, 2020.
  - Immunity for certain use of on-label Covered Countermeasures to combat COVID-19;
  - Expansion of PREP Act immunity to more health care providers who could administer the COVID-19 vaccine; and
  - Authorizes health care personnel to order/administer Covered Countermeasures for COVID-19 via telehealth to patients in other states so long as practitioner is licensed in their home state.

What are Covered Countermeasures?

a. any antiviral, any drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine manufactured, used, designed, developed, modified, licensed, or procured

i. to diagnose, mitigate, prevent, treat, or cure COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom; or

ii. to limit the harm that COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, might otherwise cause;

Covered Countermeasures (cont.)

b. a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in paragraph (a) above;

c. a product or technology intended to enhance the use or effect of a product described in paragraph (a) or (b) above; or

d. any device used in the administration of any such product, and all components and constituent materials of any such product.

Acute Hospital Care At Home

- Based on premise that many acute conditions (e.g., asthma, congestive heart failure, COPD care) can be treated safely at home with certain protocols.
- There is a waiver request process, online application.
- Six health systems are already approved.
- Program need not be “physically administered” by a hospital, but a hospital must accept responsibility for it.
- The request is to waive the CoP that requires 24/7 nursing services and immediately availability of an RN.

Acute Hospital Care At Home

- Press release: https://www.cms.gov/files/document/covid-acute-hospital-care-home-faqs.pdf
- Tricky to find FAQ: https://www.cms.gov/files/document/covid-acute-hospital-care-home-faqs.pdf
- Waiver application portal: https://qualitynet.cms.gov/acute-hospital-care-at-home

2021 Outpatient Prospective Payment System

OPPS

- Final Rule released December 2, 2020
- High points:
  - Phase out of the Inpatient Only List.
  - Adding 11 procedures to the ASC covered list.
  - Loosening expansion rule for excepted “rural provider” and “whole hospital” physician-owned hospitals.
  - Changes to supervision requirements.
  - New service categories for OPD prior authorization.

Inpatient Only List

- Previously, some procedures were ineligible for OPPS reimbursement and could only be performed on an inpatient basis.
- Final rule phases out the IPO list over 3 years.
- CY 2021, removing 298 services, including 266 musculoskeletal-related services.

Inpatient Only List

- Services will remain reimbursable on inpatient basis under the 2-midnight rule.
- Claims for these services will be exempted from site-of-service claim denials and referrals for medical review for noncompliance with the 2-midnight rule.

ASC Covered List

- Added 11 services to the covered list, including total hip arthroplasty.

Physician Owned Hospitals

- Stark has exceptions for physician-owned hospitals, including the rural provider and the whole hospital exceptions.
- To fall into the exception, the hospital may not increase the aggregate number of operating rooms, procedure rooms and beds for which it was licensed on March 23, 2010, unless CMS has granted an exception.

Physician Owned Hospitals

- Removing some restrictions on expansion available under a CMS exception.
- Removed:
  - Cap on the number of additional operating rooms, procedure rooms, and beds.
  - Limitation that expansion must only occur in facilities on the hospital's main campus.
- Allows more frequent applications for exceptions.

Supervision

- Changes the default supervision level for non-surgical extended duration therapeutic services to general (rather than direct) supervision.
- Formalizes a temporary rule from the public health emergency that these services can be initiated under general supervision.

Supervision

- Allows for direct supervision of pulmonary and cardiac rehab services via audio/visual real time communication technology.
  - Supervising practitioner must be “immediately available” but does not require “real-time presence” or “observation.”
- Continues a temporary rule related to the public health emergency, but only until the end of CY 2021.

New Service Categories for OPD Prior Authorization

- Prior authorization requirement was added last year for certain procedures.
- Cervical fusion with disc removal.
- Implanted spinal neurostimulators.
- Reaction to a large growth in volume of these procedures.

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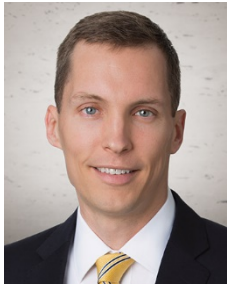

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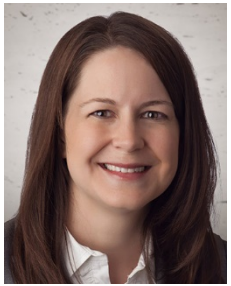

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