Health Law Webinar

Interoperability, Provider Relief Funds and More Stark/Anti-Kickback

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Agenda

- Information Blocking (Katie).
- Provider Relief Funds (Margy).
- Surprise Billing (David).
- New Anti-Kickback Safe Harbors (David).

Information Blocking

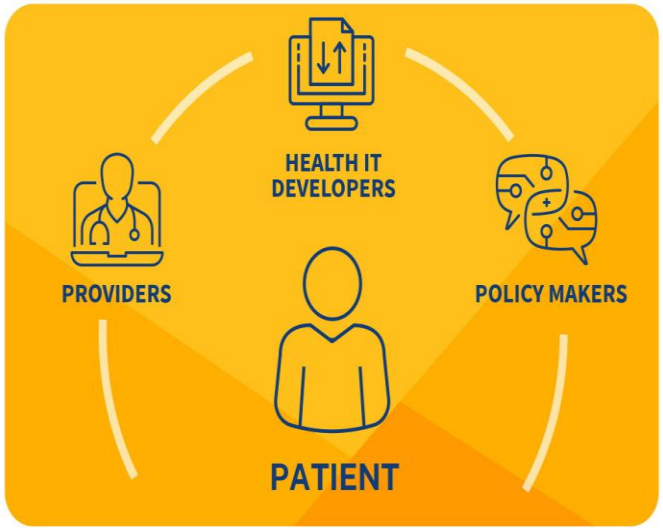
The Landscape

- Information blocking laws are part of Title IV of the 21st Century Cures Act:
  - Interoperability;
  - Information blocking; and
  - ONC Health IT Certification Program.
- Statute:

  https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf

Title IV of 21st Century Cures Act

- Goal of seamless and secure access, exchange, and use of electronic health information.



Who is Regulated?

- Health care providers;
  - Broad definition; not just a Medicare “provider.”
- Developers of Certified Health IT;
  - Individual or entity that develops or offers Certified Health IT.
- Health information networks; and
- Health information exchanges.

Health Care Provider

- “A hospital; skilled nursing facility; nursing facility; home health entity or other long term care facility; health care clinic; community mental health center; renal dialysis facility; blood center; ambulatory surgical center; emergency medical services provider; federally qualified health center; group practice; pharmacist; pharmacy; laboratory; physician; practitioner; provider operated by or under contract with the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization; rural health clinic; covered entity under 42 U.S.C. 256b; ambulatory surgical center; therapist; and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the HHS Secretary.”

What is Regulated?

- Use, access, transmission, control of “electronic health information” or “EHI.”
- Until 10/6/2022, EHI is limited to the data elements represented in the United States Core Data for Interoperability (“USCDI”) standard.
  - See Version 1: https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi
  - Quite broad; includes all clinical notes and lab results, and more.

What is Regulated?

- As of 10/6/2022, EHI is electronic PHI (as defined in HIPAA) to the extent it would be included in a designated record set (as defined in HIPAA), regardless of whether the information is maintained by a covered entity as a designated record set.
  - Does not include psychotherapy notes as defined in HIPAA or information compiled in reasonable anticipation of, or for use in, litigation.

Two Agencies at Work

- Regulations issued by two agencies:
  - Office of the National Coordinator (“ONC”); and
    - https://www.healthit.gov/curesrule/
  - Center for Medicare and Medicaid Services (“CMS”):
    - https://www.cms.gov/newsroom/fact-sheets/interoperability-and-patient-access-fact-sheet

The “Buckets” of Rules

- CMS Rule: Provider Requirements on Interoperability and Patient Access.
- CMS Rule: Payer Requirements.
- ONC Rule: Health IT Certification Criteria.
- ONC Rule: Information Blocking Prohibition.
  - We’re going to talk about this one, as it relates to health care providers.

What is Information Blocking?

Definition in CURES Act

- 42 U.S.C. 300jj-52(a)
  - Information blocking "means a practice that
    - (A) except as required by law or specified by the Secretary pursuant to rulemaking . . ., is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; **and**

Definition in CURES Act (cont.)

- 42 U.S.C. 300jj-52(a)
  - (B)(i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or

Definition in CURES Act (cont.)

- 42 U.S.C. 300jj-52(a)
  - (B)(ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information."

Breaking It Down

- Is the activity likely to interfere with, prevent, or materially discourage
  - Access to EHI (ability or means necessary to make EHI available for exchange, use, or both);
  - Exchange of EHI (ability for EHI to be transmitted between and among different technologies, systems, platforms, or networks); or
  - Use of EHI (ability for EHI, once accessed or exchanged, to be understood and acted on)?

Examples from ONC

- Practices that restrict authorized access, exchange, or use of EHI for treatment and other permitted purposes, including transitions between certified health IT technologies;
- Implementing health IT in nonstandard ways, leading to increased complexity or a burden to access, use, or exchange of EHI;
- Implementing health IT in ways likely to restrict EHI with regards to exporting information sets/transitioning between health IT systems, or in ways that would lead to fraud, waste, abuse, or impediments to innovation and advancements in health information access, exchange or use.

Helpful Examples from ONC

- EHR developer refuses to export EHI without charging an export fee when provider decides to switch systems.
- A developer requires extensive vetting of third-party applications before the applications can access the developer's product.
- A provider limits sharing of information with other providers or users of other IT systems.

Helpful Examples from ONC

- Health system requires physicians to adopt its EHR platform and does not connect with outside systems or competing hospitals.
- A certified EHR developer requires a third-party app developer to pay a fee to access the EHR system of the third-party app developer's customer.

Other Possible Examples

- Policy not to share mental health records without the patient's express written consent for each request?
- Small clinic cannot afford to connect to hospital's EHR?
- Policy not to disclose "outside" records?
- Clunky patient portal?

Other Possible Examples

- Not providing same-day access to EHI in a form requested by a patient or a health care provider when you have the capability to do so?
- Not offering access to EHR to affiliate providers with hospital privileges when affiliate providers are off-site?

There are Eight Exceptions

- Exceptions that involve **not fulfilling requests** to access, exchange, or use EHI.
- Exceptions that involve **procedures for fulfilling requests** to access, exchange, or use EHI.

Effect of Exceptions

- “We appreciate that most actors will want to meet an exception to guarantee that their…practices do not meet the definition of information blocking…”
- Failure to meet an exception does not mean a certain practice is “information blocking.”
  - But meeting an exception is a guaranteed protection from CMPs or other “disincentives.”

Exceptions That Involve Not Fulfilling Requests to Access, Exchange, or Use EHI

- Preventing harm.
- Privacy.
- Security.
- Infeasibility.
- Health IT performance.

Preventing Harm Exception

- A practice likely to interfere with the access, exchange, or use of EHI is not considered information blocking if it is reasonable and necessary to prevent harm to another person.
  - Must hold a reasonable belief that the practice will substantially reduce a risk of harm AND
  - Practice must be no broader than necessary

THEN…

Preventing Harm Exception

- Must satisfy at least one condition from each of the following:
  - Type of risk: (1) Determined on individualized basis, exercising professional judgment by health care professional with clinician-patient relationship; or (2) arise from data that is known/reasonably suspected to be misidentified, corrupt due to technical failure, or erroneous;
  - Type of harm: (1) Reasonably likely to endanger life or physical safety of patient or another person; or (2) reasonably likely to cause substantial harm.
  - Implementation basis: (1) Consistent with an organization policy; or (2) based on facts and circumstances known/reasonably believed and based on expertise relevant to implementing the practice.

Preventing Harm Exception

- Patient has a right to request a review of an individualized determination of risk of harm.
- Subject of many FAQs.

Privacy Exception

- It is not information blocking to not fulfill a request to access, exchange, or use EHI in order to protect an individual's privacy.
- Must meet one of four criteria.

Privacy Exception

1. Precondition to release not met (e.g., consent under state law).
   - Several subrequirements.
2. Health IT developer of certified health IT not covered by HIPAA may interfere with EHI for a "privacy-protective purpose."
3. Denial of individual's request for EHI is consistent with the right under HIPAA to deny access for:
   - Psychotherapy notes;
   - Anticipation of trial;
   - CLIA;
   - Correctional institution;
   - Temporarily agreed not to have access;
   - In records subject to Privacy Act (federal agency records); and
   - Info obtained from third party confidentially and revealing info would reveal identity of the person.
4. Respecting individual's request not to share information.
   - Pretty closely tracks HIPAA's requests for restrictions on use.

Security Exception

- Not information blocking to protect the security of EHI if the practice is
  - Directly related to safeguarding confidentiality, integrity, and availability of EHI;
  - Tailored to specific security risks;
  - Implemented in a consistent and non-discriminatory manner; and
  - The organization implements a qualifying organizational security policy, or the organization must have made a qualifying security determination in each case of risk and lack of alternatives.

Infeasibility Exception

- It is not information blocking to not fulfill a request due to the infeasibility of the request if one of the following is met:
  - Uncontrollable event;
    - Natural/human disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike, telecom/internet interruption, act of military, civil or regulatory authority.
  - Segmentation;
    - Cannot unambiguously segment the requested EHI;
  - Infeasibility under the circumstances;
    - Contemporaneous written record or other documentation shows (specific) factors that led to determination; cannot discriminate and make it infeasible only for some (like a competitor or someone that actor cannot charge)

AND

  - Must respond within 10 business days of receipt with the reason(s) the request is infeasible.

Health IT Performance Exception

- It is not information blocking to maintain or improve health IT via temporary unavailability, or degrade performance to benefit of overall IT performance if the practice is:
  - Implemented for no longer than necessary to maintain/improve;
  - Implemented consistently and non-discriminatorily; and
  - Meets certain requirements if unavailability/degradation is initiated bythe health IT developer of certified health IT, HIE, or HIN.
- If the unavailability is in response to risk of harm or security risk, only need to comply with the Preventing Harm or the Security Exception.

Health IT Performance Exception

- An actor can take action against a third-party app that is negatively affecting the health IT's performance, if the practice is:
  - For no longer than necessary to resolve negative impacts;
  - Implemented in a consistent and non-discriminatory manner; and
  - Consistent with existing SLAs, where applicable.

Exceptions That Involve Procedures for Fulfilling Requests to Access, Exchange or Use EHI

- Content and manner.
- Fees.
- Licensing.

Content and Manner Exception

- It is not information blocking to limit the content of a response to, or the manner of fulfilling, a request to access, exchange, or use EHI.
- Content that must be provided to satisfy the exception:
  - Must respond with USCDI data elements (if prior to 10/6/2022); or
  - All EHI (if on or after 10/6/2022).

Content and Manner Exception

- Manner of responding:
  - An actor may fulfill a request in an alternative manner than the manner in which it is requested when the organization is
    - Technically unable to fulfill the request in any manner requested; or
    - Cannot reach agreeable terms with the requestor to fulfill the request.
- If the request fulfilled in alternative manner, the actor must comply with a certain order of priority and must satisfy Fees Exception and Licensing Exceptions.

Fees Exception

- Charging fees for accessing, exchanging, or using EHI will not be considered information blocking if the fee:
  - Meets the basis for the Fees Exception (see next slide)
  - Is not specifically excluded:
    - Prohibited by HIPAA's right of access (must be reasonable, cost-based);
    - Based in any part on the electronic access of an individual's EHI by the individual, their personal representative, or another person or entity designated by the individual;
    - To perform an export of electronic health information via the capability of health IT certified to § 170.315(b)(10) for the purposes of switching health IT or to provide patients their electronic health information; or
    - To export or convert data from an EHR technology that was not agreed to in writing at the time the technology was acquired.
  - Complies with Conditions of Certification in 170.402(a)(4) for health IT developers.

Fees Exception

- Fees must be:
  - Based on objective and verifiable criteria, uniformly applied;
  - Reasonably related to the actor's costs of providing the access, exchange, or use;
  - Reasonably allocated among all similarly situated persons or entities to whom the technology or service is supplied, or for whom the technology is supported; and
  - Based on costs not otherwise recovered for the same instance of service to a provider and third party
- Fees must not be based on:
  - Whether the requestor or other person is a competitor, potential competitor, or will be using the EHI in a way that facilitates competition with the actor;
  - Sales, profit, revenue, or other value that the requestor or other persons derive or may derive from the access, exchange, or use of the electronic health information;
  - Costs the actor incurred due to the health IT being designed or implemented in a nonstandard way, unless the requestor agreed to the fee;
  - Costs associated with intangible assets other than the actual development or acquisition costs of such assets
  - Opportunity costs unrelated to the access, exchange, or use of electronic health information; or
  - Any costs that led to the creation of intellectual property, if the actor charged a royalty for that intellectual property pursuant to § 171.303 and that royalty included the development costs for the creation of the intellectual property.

Licensing Exception

- Actors may condition access to and use of its interoperability elements for accessing EHI to acceptance of a license agreement, if its licensing program is applied in a nondiscriminatory manner and meets certain additional conditions, including:
  - Conditions for negotiating a license for an “interoperability element”: begin negotiations with a requestor within 10 business days from receipt of request and negotiate a license within 30 business days from receipt of request;
  - Licensing conditions must include:
    - Scope of rights, reasonable royalty, non-discriminatory terms, collateral terms (no non-competes, exclusive deals, etc.), NDA ok if no broader than necessary.
  - Additional conditions relating to provision of interoperability elements.

When are the Rules Effective?

- There is no longer a compliance date and a subsequent enforcement date.
- The new “applicability date” for the ONC information blocking rules is 4/5/2021.

What are the Stakes?

- Enforcement = ??
  - OIG proposed a rule in April 2020 for imposing civil money penalties (“CMPs”) for information blocking. The rule applies only to Heath Information Networks/Health Information Exchanges and developers of certified health IT.
  - Enforcement begins 60 days after publication of the final rule.
  - Factors for imposing CMPs in proposed rule:
    - Number of patients, providers affected; number of days of information blocking practice.
  - Proposed maximum penalty of $1M per violation.

What are the Stakes?

- What about health care providers?
- Providers could be subject to “appropriate disincentives” in future rulemaking.
- Complaint submission solicited by ONC via website portal.

Provider Relief Fund

Provider Relief Fund

- Established under the CARES Act.
- “General” and “Targeted” Distributions.
  - Three phases of General Distributions to date.
  - Targeted Distributions included SNFs, rural, tribal, safety net hospitals, etc.
- Eligibility originally based on Medicare FFS payments in 2019; expanded in subsequent distributions.

Use of Funds

- Funds must be used “to prevent, prepare for, and respond to coronavirus.”
- Two categories of coverage:
  - health care related expenses attributable to coronavirus; or
  - lost revenues that are attributable to coronavirus.
- Funds must be expended no later than June 30, 2021.

Use of Funds: Expenses

- The term "healthcare related expenses attributable to coronavirus" is a broad term that may cover a range of items and services purchased to prevent, prepare for, and respond to coronavirus:
  - supplies and equipment used to provide health care services for possible/actual COVID-19 patients;
  - workforce training;
  - developing and staffing emergency operation centers;
  - reporting COVID-19 test results to federal, state, or local governments;
  - building or constructing temporary structures to expand capacity for COVID-19 patient care or to provide health care services to non-COVID-19 patients in a separate area from where COVID-19 patients are being treated; and
  - acquiring additional resources, including facilities, equipment, supplies, health care practices, staffing, and technology to expand or preserve care delivery.

Use of Funds: Expenses

When reporting my organization's healthcare expenses attributable to coronavirus, how do I calculate the "expenses attributable to coronavirus not reimbursed by other sources"?

Healthcare related expenses attributable to coronavirus may include items such as supplies, equipment, information technology, facilities, employees, and other healthcare related costs/expenses for the calendar year. The classification of items into categories should align with how Provider Relief Fund recipients maintain their records. Providers can identify their healthcare related expenses, and then apply any amounts received through other sources…that offset the healthcare related expenses. Provider Relief Fund payments may be applied to the remaining expenses or costs, after netting the other funds received or obligated to be received which offset those expenses. The Provider Relief Fund permits reimbursement of marginal increased expenses related to coronavirus.

Use of Funds – Expenses

Can Provider Relief Fund payments be used to support COVID-19 vaccine distribution?

Provider Relief Fund payments may be used to support expenses associated with distribution of a COVID-19 vaccine licensed or approved by the Food and Drug Administration (FDA) that have not been reimbursed from other sources or that other sources are not obligated to reimburse. Funds may also be used ahead of an FDA-licensed or approved vaccine becoming available. This may include using funds to purchase additional refrigerators, personnel costs to provide vaccinations, and transportation costs not otherwise reimbursed.

…If reimbursement does not cover the full expense of administering vaccines, Provider Relief Funds may be used to cover the remaining associated costs.

Use of Funds: Expenses

Are expenses related to securing and maintaining adequate personnel reimbursable expenses under the Provider Relief Fund?

Yes, expenses incurred by providers to secure and maintain adequate personnel, such as offering hiring bonuses and retention payments, child care, transportation, and temporary housing, are deemed to be COVID-19-related expenses if the activity generating the expense was newly incurred after the declaration of the Public Health Emergency and the expenses were necessary to secure and maintain adequate personnel.

Use of Funds: Lost Revenues

- Under the Consolidated Appropriations Act, 2021 (H.R. 133), HHS is required to permit providers to calculate lost revenues using the guidance issued as of June 2020:
  - Providers may use any reasonable method of estimating the revenue during March and April 2020 compared to the same period had COVID-19 not appeared. For example, if you have a budget prepared without taking into account the impact of COVID-19, the estimated lost revenue could be the difference between your budgeted revenue and actual revenue. It would also be reasonable to compare the revenues to the same period last year.
  - H.R. 133 sets the deadline for having established such a budget at March 27, 2020.

Reporting & Audits

- Providers who received ≥ $10,000 in aggregate PRF payments must report as directed by HHS
  - Deadline: Use of funds as of December 31, 2020 must be reported by February 15, 2021. Recipients with funds unexpended after December 31, 2020, have six more months to use remaining funds, and then must submit a second and final report by July 31, 2021.
- Single Audit requirements apply to recipients of ≥ $750,000.

Uncertainty Remains…

- FAQs do not yet align with H.R. 133.
- “Separate reporting requirements may be announced in the future.”

Resources

- HHS FAQs
  - https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/faqs/provider-relief-fund-general-info/index.html
- Reporting
  - https://www.hhs.gov/sites/default/files/post-payment-notice-of-reporting-requirements-november-2020.pdf
- Audit Guidance
  - https://www.whitehouse.gov/wp-content/uploads/2020/12/2020-Compliance-Supplement-Addendum_Final.pdf

Surprise Billing

"Dear Henry: Where were you? We waited and waited but finally decided that . . ."

No Surprises Act

- Amends the Public Health Service Act 42 U.S.C. § 300gg.
- Takes effect 1/1/21.
- Incredibly dense text.
- Applies to emergency services, air ambulance services, ASCs and in-network hospital services. Does not apply to ground ambulance.
- Applies to physician services at hospitals/ASCs.

No Surprises Act

- May not charge the patient a higher co-pay or deductible than they would pay for in-network services.
- Does not limit the bill or require the insurer to pay.
- Baseball arbitration for disputes.

No Surprises Act

- Some out-of-network physicians may, upon receipt of written consent, charge a higher rate for out-of-network services.
- Emergency medicine, anesthesiology, pathology, radiology and neonatology are prohibited from balance billing, even with consent.
- Same limitation for diagnostic services, including radiology and laboratory services.

Stark and Anti-kickback

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
- Anti-kickback: 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.
- David, I thought Preambles weren't binding?!

Important Reminder

"Arrangements are not necessarily unlawful because they do not fit in a safe harbor. Arrangements that do not fit in a safe harbor are analyzed for compliance with Federal anti-kickback statute based on the totality of their facts and circumstances, including the intent of the parties."

85 F.R. 77685.

New Safe Harbors

- Eight new safe harbors including:
  - Point of sale at reductions in price for prescription drugs.
  - BPM service fees.
  - Care coordination to improve quality outcomes and efficiency.
  - Value-based arrangements with substantial downside risk.
  - Value-based arrangements with full financial risk.
  - Arrangements for patient engagement.
  - Cybersecurity technology and related services.
  - ACO beneficiary incentive program.

Changed Safe Harbors

- Electronic health records
  - Modifies interoperability terms, removes sunset and removes prohibition on donation of equivalent technology. Clarifies cybersecurity donations.
- Personal services and management contracts
  - Increase flexibility for part-time/intermittent arrangements lacking predictable compensation and protections for outcomes-based payments.
- Warranties
  - Modifying the definition and allowing multiple warranties
- Local transportation
  - Expanding mileage to 75 miles in rural areas and deleting mileage limits for patients returning home from the hospital. Clarifying ride share can be used.
- ACO Beneficiary Incentives
  - New definition of remuneration

What is Remuneration?

- The CMP law SSA § 1128A(a)(5) and the anti-kickback statute SSA § 1128B(b) are different.
- CMP includes anything “that the benefactor knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner or supplier of any item or service.”
- Anti-kickback exceptions protect under CMP, but not vice-versa.

Do They Mean This?

"Many beneficial arrangements do not implicate the anti-kickback statute and do not need protection. For example, the parties may be exchanging nothing of value between them or the arrangements might involve no federal healthcare program patients or business."

85 F.R. 77685

Not Exactly…

- "Generally speaking, the Federal Anti-Kickback statute is not implicated for financial arrangements limited solely to patients who are not Federal healthcare program beneficiaries. However, to the extent the offer of renumeration pursuant to an arrangement involving only non-Federal healthcare program beneficiaries is intended to pull through referrals of Federal healthcare program beneficiaries or business, the Federal Anti-Kickback statute would be **implicated** and potentially violated."

85 F.R. 77693

Or Maybe They Do????

"However, we remind readers that even if care coordination services constitute remunerations, the Federal Anti-Kickback statute is not necessarily implicated. For example, the Federal Anti-Kickback statute generally is not implicated for financial arrangements limited solely to patients who are not Federal healthcare program beneficiaries. Further, depending on the facts and circumstances (including the intent of the parties), the provisions of care coordination services may **implicate** the Federal Anti-Kickback statute **but not violate it.**"

85 F.R. 77742

Caveat Owner?

- “We continue to be concerned there is potential for entities under common ownership to use value-based arrangements to effectuate payment-for-referral schemes, but we also believe that the combinations of safeguards we are adopting in the safe harbors should mitigate these risks.”

85 F.R. 77701

Cash or In-Kind

- In the value-based arena, cash payments are only protected by the safe-harbors with substantial financial risk, .952(ff) and (gg).
- (ee) only protects non-monetary compensation.

Cash or In-Kind

- CMS discusses a hospital providing a nurse navigator at a SNF. That can qualify for safe harbor protection. The cash to pay for a nurse navigator cannot.

85 F.R. 77735

Organizations Ineligible for Value-Based Safe Harbors

- Pharmaceutical manufacturers.
- Distributors and wholesalers.
- Pharmacy benefit managers.
- Laboratory companies.
- Pharmacies that primarily dealing with compounded drugs.
- Entities or individuals that sell or rent DMEPOS (other than a pharmacy or a physician or provider,)
- Medical device distributors and wholesalers.

Compounding Pharmacies

- “We remain deeply concerned about fraud and abuse in the compounding pharmacy industry…spending for compounded topical drugs was 24 times higher in 2016 than it was in 2010, which raises concerns about fraud and abuse.”

85 F.R. 77715

Patient Notification

- CMS rejected requiring patient notification. It would impose an administrative burden without materially lowering the risk of fraud and abuse.
- “Such notices, if executed poorly, could confuse patients.”

85 F.R. 77744

Marketing

- There is a lengthy discussion on page 77745 about marketing. The OIG believes that door-to-door marketing and telephone solicitations “can be extremely coercive.”
- Particular concerns for seniors, Medicaid beneficiaries and other “vulnerable patients.”

Odd View of Marketing and Remuneration

- If a SNF or home health agency places a staff member at a hospital to assist in discharge planning, CMS deems it acceptable if the staff member works only with patients who have already selected at SNF/HHA.
- If the SNF or HHA is there to market generally, “the arrangement would not comply with this requirement because the remuneration being exchanged pursuant to the agreement . . . would be exchanged for the purpose of engaging in marketing.”
- Direct mail can’t be protected under the VBE exception.

85 F.R. 77745.

Tell Me Why

- VBE remuneration must be directly connected to the value-based purchase.
- If the target population is hip replacement, hiring a staff member to coordinate post-acute care for hip patients fits the safe harbor, staff who coordinate all post-surgical transitions don’t fit the safe harbor.
- Can you just have a broader target population?

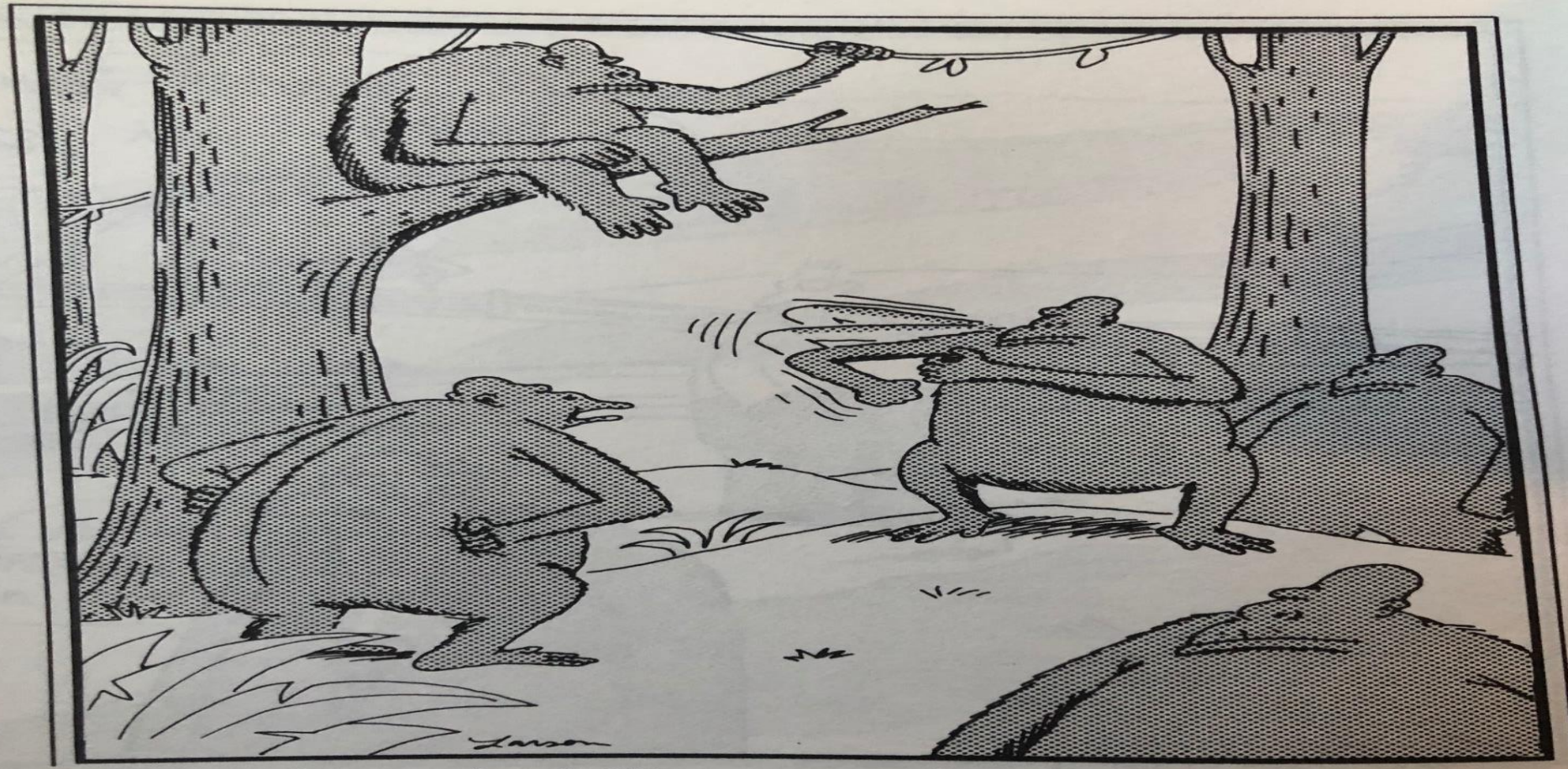
Beware of State Law

- The VBE full-risk safe harbor may require a structure that runs afoul of state insurance laws.
- CMS recognizes this and suggests considering other safe harbors or being comfortable outside the safe harbor.

Full Financial Risk

- To meet the full risk safe harbor, there must be risk for all services, but it does not require complete risk on each service. Reinsurance/stop loss is acceptable.
- “Full” refers to the scope of the services, not the scope of the risk.

85 F.R. 77772



"For crying out loud, Warren . . . can't you just beat your chest like everyone else?"

Warranties

- Commenters noted that the safe harbor won't protect warranties where Medicaid covers the service in question. CMS explains that advisory opinion 18-10 indicated the OIG wouldn't challenge such an arrangement.
- Another reminder about the narrow scope of the safe harbors.

85 F.R. 77852

Narrow VBE Protection

- “Where VBE participants exchange remuneration that the recipient VBE participant then transfers to its patients (for example, where one VBE participant provides fitness trackers to another VBE participant, who in turn furnishes the fitness tracker to the patient) the care coordination arrangement’s safe harbor would be available only to protect the remuneration exchanged between the VBE participants. The parties may look to the patient engagement and support safe harbor to protect the remuneration from the VBE participant to the patient.”

85 F.R. 77704

Thinking Like A Lawyer

- "A commenter suggested that we revise this term to require the 'coordination *or* management of care' instead of the 'coordination *and* management of care.'
- Response: …we are not adopting the commenter's suggestion…we are concerned that management activities, standing alone, would not be appropriately patient focused to achieve the intent of the value based safe harbors."

85 F.R. 77723

Evidence-Based?

- The original proposal required “evidenced based metrics.”
- CMS “did not intend to require protective arrangements be grounded in experimental research, randomized clinical trials and the like.
- They reframed the term as ‘legitimate.’”

85 F.R. 77727

Revise vs. Rebase

- CMS originally planned to require rebasing outcomes measures.
- They acknowledge rebasing may not be necessary for all legitimate outcome's measures.
- It would seek periodic assessment, sometimes annually, whereas others might reasonably be every two to three years.

85 F.R. 77731

The Curse of Success

- Successful cost reduction programs make further cost reductions more difficult.
- The preamble recognizes this and acknowledges it can be proper to use national or regional data as a target.
- Use a bona fide benchmark.

85 F.R. 77758


FLY
SUX

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