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Navigating Patient Needs Remotely: Addressing Challenges in Patient Access

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Topics for Today's Session

- AKS Refresher
- Addressing Patient Insurance Loss/Economic Disruption
  - Free trial/temporary supply
  - Copay subsidies
  - PAP eligibility rules and assessments
- Patient Enrollment in a Virtual Environment
- Patient Access to Infused Medications
- Social Distancing and Nurse Support
- Virtual Communications with Patients

AKS Refresher

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- **The Anti-Kickback Statute (AKS) prohibits "any person" from:**
  - o Knowingly and willfully
  - o Offering, paying, soliciting, or receiving
  - o Anything of value ("remuneration")
  - o Directly or indirectly
  - o To induce a person to purchase, prescribe or recommend a product or service reimbursable under a federal healthcare program

AKS Exceptions and Safe Harbors

- If the payment or transfer of value complies with a statutory exception and/or regulatory safe harbor, it is protected from liability
  - Where possible, structure arrangements with vendors consistent with the personal services safe harbor
- **The AKS has no exception or safe harbor for patient support programs**
  - HHS OIG has issued relevant guidance for certain types of arrangements, e.g.,
    - Limited reimbursement support
    - Manufacturer copayment coupon programs
    - Manufacturer patient assistance programs (PAPs)
    - Donations to independent charity copay PAPs
- If an arrangement does not fit within a safe harbor or current OIG guidance, a company can seek an OIG advisory opinion

COVID-19 Public Health Emergency Declaration

- HHS declared a public health emergency for the US beginning January 31, 2020
- OIG will exercise enforcement discretion as to certain practices by healthcare providers
  - *OIG Policy Statement Regarding Application of Certain Administrative Enforcement Authorities Due to Declaration of Coronavirus Disease 2019 (COVID-19) Outbreak in the United States as a National Emergency* (April 3, 2020)
  - *OIG Policy Statement Regarding Physicians and Other Practitioners That Reduce or Waive Amounts Owed by Federal Health Care Beneficiaries for Telehealth Services During the 2019 COVID-19 Outbreak* (March 17, 2020)
- OIG has not issued a COVID-19 safe harbor or announced that it will exercise enforcement discretion for manufacturer patient support programs

Prudential Factors

- According to OIG, "[T]he courts have identified several potentially aggravating considerations that can be useful in identifying arrangements at greatest risk of prosecution"
  - "Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making?
  - "If the arrangement or practice involves providing information to decisionmakers, prescribers, or patients, is the information complete, accurate, and not misleading?
  - "Does the arrangement or practice have a potential to increase costs to the federal health care programs, beneficiaries, or enrollees?
  - "Does the arrangement or practice have the potential to be a disguised discount to circumvent the Medicaid Rebate Program Best Price calculation?
  - "Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?
  - "Does the arrangement or practice raise patient safety or quality of care concerns?"

86 Fed. Reg. 23731, 23734 (May 5, 2003).

Addressing Patient Insurance Loss/Economic Disruption

Free Trial/Temporary Supply

- Manufacturers may choose to offer limited-time, free supplies of product to eligible patients who are:
  - New to therapy
  - Experiencing a delay or interruption of coverage
- Relevant OIG Guidance
  - AO 08-04—Up to 10-week voucher program with PDMA-like controls and no clinical barriers to switching
  - PAP guidelines—Providing free product "outside the Part D benefit only during the coverage gap pose[s] a heightened risk of fraud and abuse"
  - AO 15-11—Up to 60-day free trial program allowed for breakthrough cancer drug under specific circumstances
  - AO 18-14—Negative OIG opinion regarding proposal to provide free product to hospital inpatients
- Government price reporting implications if free product is contingent on a purchase requirement

Prudential Factors

- Does the product treat a disease for patients who are vulnerable to COVID-19 (e.g., certain respiratory products or cardiac products)?
- Is it important to patient safety that patients not abruptly discontinue therapy or lower the dose?
- Is the product the only one available in its class? Is it more effective or safer than alternatives?
- Is the product less expensive than alternatives (is there no generic alternative)?
- Is it important that patients start therapy quickly for better clinical outcomes?
- Are there few/no clinical barriers to switching therapy?
- Does the proposed arrangement provide little/no financial benefit to providers?

Assistance for OOP Costs

- OIG does not permit manufacturer coupon programs for federal program beneficiaries
  - Cost-sharing subsidies for Federal Program patients may "lock[] beneficiaries into the manufacturer's product, even if there are other equally effective, less costly alternatives . . . ." OIG 2005 PAP Special Advisory Bulletin
  - "Manufacturers that offer copayment coupons may be subject to sanctions if they fail to take appropriate steps to ensure that such coupons do not induce the purchase of Federal health care program items or services, including, but not limited to, drugs paid for by Medicare Part D." OIG 2014 Coupon Special Advisory Bulletin
- OIG allows manufacturer donations to independent third-party foundations that subsidize federal program beneficiary copays
- During the COVID-19 Emergency, OIG has announced enforcement discretion for physicians and other providers that reduce or waive amounts owed by federal program beneficiaries (e.g., for telehealth services)
- OIG has not extended this guidance to manufacturer copay subsidies

Free Drug PAPs

- Manufacturer PAPs
  - Free or reduced-price product for financially needy patients who meet specified eligibility criteria
  - PAPs serve as an “important safety net” for patients in need
- OIG’s PAP Operating Outside Part D Guidelines
  - Provide assistance for the whole coverage year (or remaining portion), even if beneficiary’s use of the drug is periodic
  - Provide assistance based on reasonable, uniform and consistent measures of financial need, without regard to the providers or plans used by the patient
  - Notify Part D plans that assistance is provided
  - Notify patients not to bill or count product costs towards TrOOP
  - Maintain records of assistance provided

Free Drug PAPs: Changes to PAP Rules

- Possible COVID-related eligibility rules/process changes
  - Eliminate or relax income documentation requirements
  - Eliminate income criteria for patients who have lost employment and/or insurance due to COVID-19
  - Add exceptions process for patients who have lost employment/income or insurance due to COVID-19
- OIG has issued no COVID-related guidance on this subject
- Evaluate under OIG PAP guidance, prudential factors

Patient Enrollment in a Virtual Environment

Patient Enrollment—HIPAA Rules

- **Enrollment form: Physician to HUB**
  - As HIPAA-covered entity, physician needs authorization to disclose patient's personal ("protected") health information (PHI) to HUB
  - HUB is not a "business associate" of the physician
  - HUB is not providing "health care" to the patient
  - HUB is not paying for the patient's health care
- **HIPAA authorization requirements**
  - Patient authorization must be:
    - In writing
    - Signed by patient or personal representative
    - Separate from other consents

Beyond HIPAA—State Law Requirements

- **States generally**
  - o Authorization must be in writing and signed
  - o Some states limit term of validity (prescribe expiration date)

- **California**
  - o Requires specific type size (14-point)
  - o Applies to disclosures (and arguably uses) by pharmaceutical companies -- including their agents (e.g., a HUB)

Options to Obtain Patient Authorizations Virtually

- **Mail**
  - o Physician mails enrollment form to patient
  - o Patient signs authorization; sends to HUB
- **Website**
  - o HUB posts authorization form on website
  - o Physician provides patient with website URL
  - o Patient prints authorization, signs and sends to HUB
  - o OR: Website offers option for patient to click “I agree”
- **Email**
  - o Physician emails authorization to patient
  - o Patient prints, signs and sends to HUB
  - o OR: patient reads authorization, replies “I agree” in email message

Are the Webform and Email “I Agree” Options OK?

- **Are they electronic signatures?**
  - *Electronic signature*: “An electronic sound, symbol, or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.”
  - *Electronic*: “Relating to technology having electrical, digital, magnetic, wireless, optical, electromagnetic, or similar capabilities”
- **Are they valid signatures?**
  - “A signature . . . may not be denied legal effect, validity, or enforceability solely because it is in electronic form.”
  - “If the law requires a signature, an electronic signature satisfies the law.”

Quotes from Federal E-Sign Act and State UETA

What About Texting the Authorization to the Patient?

- **Idea**
  - o Send patient authorization via text
  - o Patient prints authorization, signs and sends to HUB

    OR
  - o Patient reads authorization, replies “I agree” by text

- **Problems**
  - o Who will send the text to the patient and get the reply?
  - o What about format requirements, such as California 14-point type requirement?

What About Getting a Verbal Authorization?

- **Idea**
  - o An electronic signature includes “an electronic sound”
  - o Call patient, read authorization to patient
  - o Record patient’s “I agree” (electronic signature)

- **Problems**
  - o Who will call the patient and record the response?
  - o Is the patient signing a “written” authorization?

Patient Access to Infused Medications

Nurse Support Background

- Manufacturers of specialty drugs sometimes offer nurse support to help patients understand their medication, providing education on:
  - Administration and dosing (particularly for self-administered injectable or infused medications)
  - Common side effects
  - Compliance and adherence
- Nurse support is designed to facilitate the safe use of a medication in accordance with the treating physician's instructions
- OIG has said that manufacturers can provide "limited" support in connection with the sale of their products
  - Part of the purchase of a drug

Infused Drug Access During COVID-19

- Many physician practices/clinics and hospital out-patient departments are not providing elective procedures, including drug infusions
- Improving access to infused drugs during COVID-19
  - Nurse support
  - Facilitate home infusion
- OIG has issued no COVID-related guidance here
- Evaluate under prudential factors

Social Distancing and Nurse Support

Social Distancing Considerations

- Companies that use nurses or clinical educators to educate patients on drug administration, safety or other topics may conduct virtual patient education sessions
  - Adapt standard compliance guidance for virtual sessions, e.g.,
    - Use pre-approved materials only
    - Monitor compliance with company requirements and procedures (virtual ride-along)
  - Ensure that contract nurses are not paid for travel and lodging expenses
  - Refer questions regarding COVID-19 to the patient's HCP
- For in-person nurse visits, consider potential for spreading COVID
  - Confirm what precautions the vendor uses to prevent exposure/infection
  - Check agreements regarding indemnification, insurance obligations w/r/t any injury due to COVID-19 transmission
  - Check liability insurance

Virtual Communications with Patients

Web-based Conferencing—Security Issues

- Data security risks—the Zoom example
  - Installer gained access to user's computer
  - Data transmitted to Facebook and routed through China
- Other remote communications options
  - Public-facing remote communication products, such as TikTok, Facebook Live, Twitch, or a chat room such as Slack—NOT SECURE
  - Private-facing products such as Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, WhatsApp video chat, Skype—LESS RISKY
  - More secure products include Skype for Business, Zoom for Healthcare
- Secure platforms generally provide:
  - End-to-end encryption
  - Individually established accounts with usernames and passwords
  - Individual ability to control video and audio

Text Messaging

- Telephone Consumer Protection Act, 47 USC § 227 (TCPA)
  - o Implemented by Federal Communications Commission (FCC)

- TCPA enforcement
  - o FCC enforcement actions
  - o Private right of action—frequent class actions
  - o $500 **per violation**
  - o Treble damages for each willful or knowing violations

- State laws are not preempted

Examples of TCPA Settlements

• Caribbean Cruise Line	$56–76 million	Sep. 2016
• Dish Network	$61 million	Oct. 2017
• US Coachways	$49.9 million	Nov. 2016
• FreeEats.com/AIC Comm.	$32.4 million	Sep. 2017
• Midland Credit	$20.5 million	July 2016
• Uber	$20 million	Sep. 2017

TCPA Rules for Autodialed/Prerecorded Calls/Texts

- Purely *informational* (not telemarketing) artificial voice or prerecorded calls may be made to *residential* landlines without any consent
- Purely *informational* autodialed or artificial voice/prerecorded calls may be made to *wireless* lines only if there is *prior express consent*
- *Any telemarketing* calls using a prerecorded message or artificial voice, and any autodialed telemarketing calls to cell phones, require *prior express **written** consent*
- Limited exceptions for:
  - Emergency calls
  - Calls by tax-exempt nonprofits
  - Certain HIPAA-covered health care calls

Questions?

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