Trends in Healthcare Fraud Enforcement

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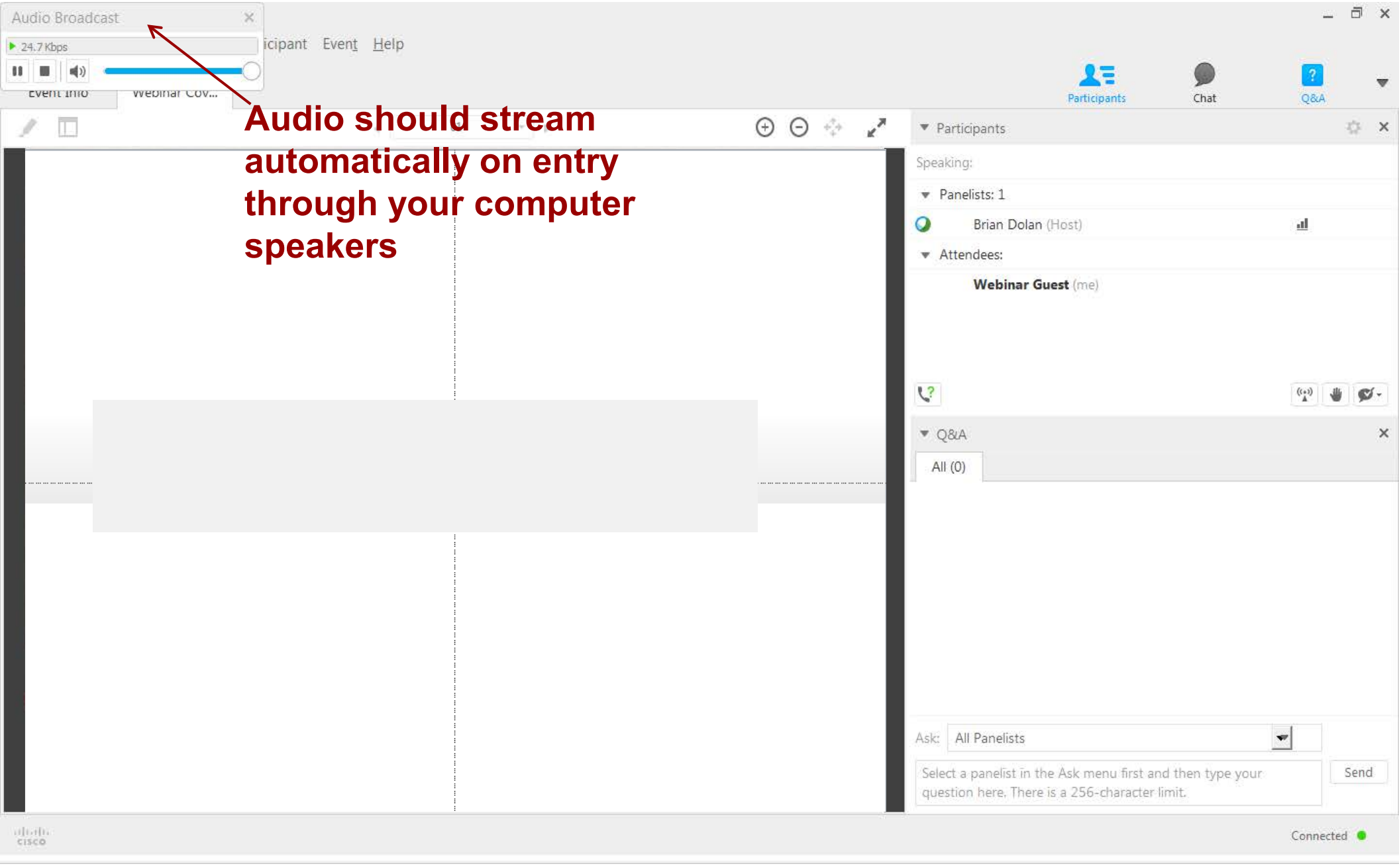
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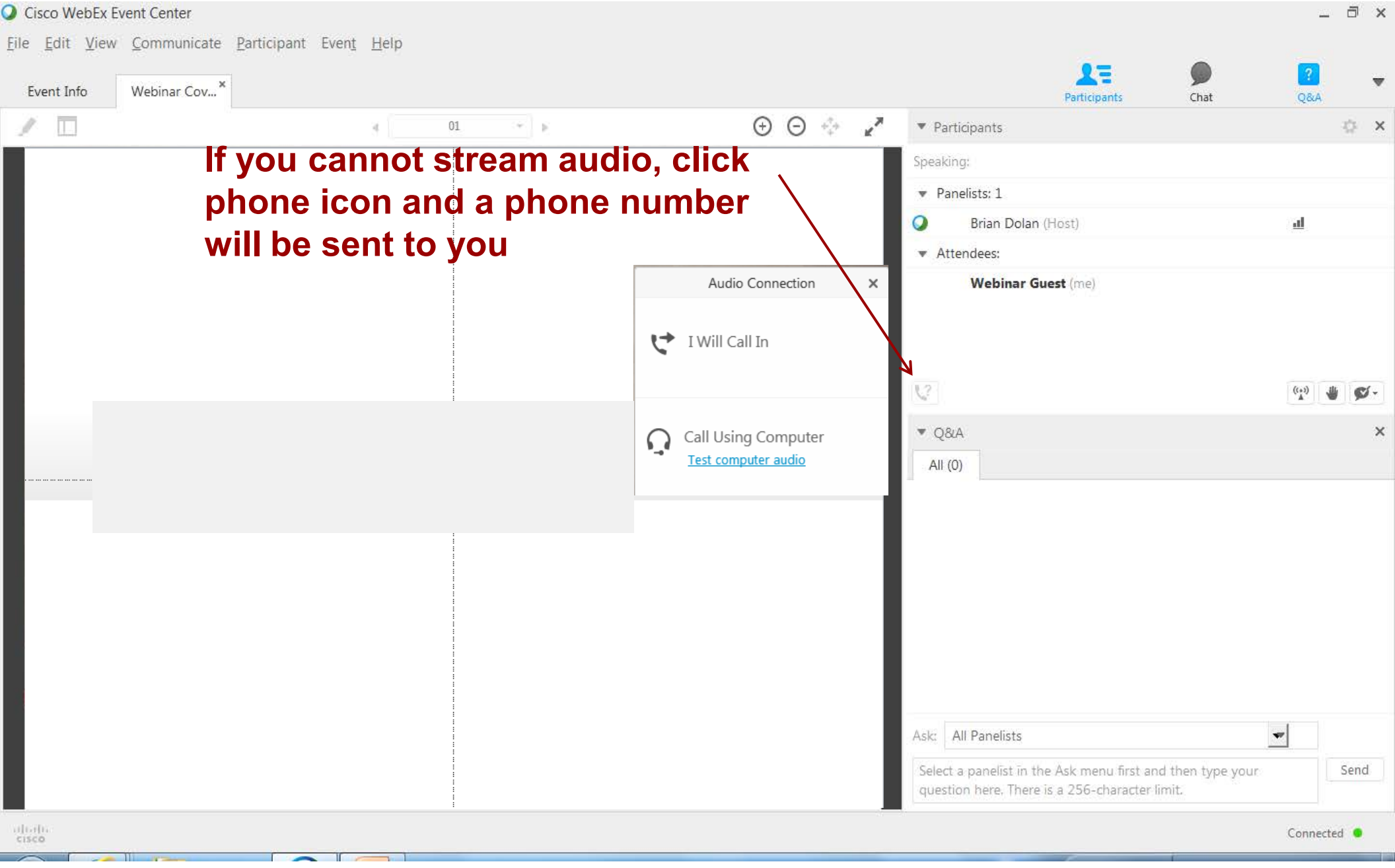
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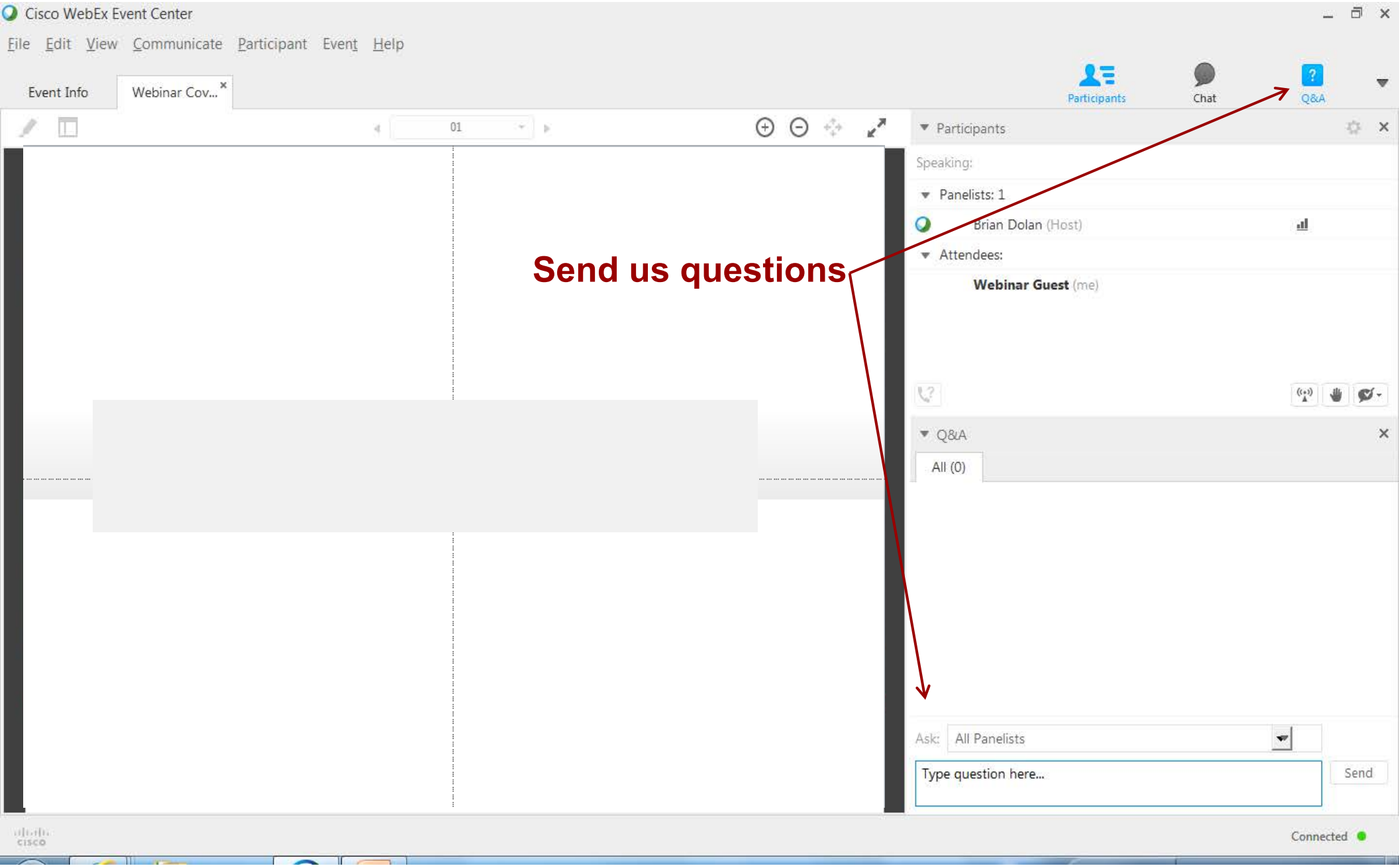
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- Represents clients in government investigations, health care fraud and abuse matters, and internal corporate investigations.
- A former federal prosecutor and experienced trial lawyer, Ms. Hooker represents pharmaceutical companies, medical device manufacturers, payors, health care providers, and other entities and individuals in federal criminal, civil and state attorney general investigations and enforcement actions.
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We will be starting at 12:00pm ET. There is currently no audio until we start.

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Themes of Recent Enforcement Actions

- Medical Necessity
- Patient Quotas
- Opioid Diversion
- Increased Use of Travel Act

Recent Enforcement Actions: Medically Unnecessary Drugs and Treatments

Medical Necessity

- What is it?
  - Center for Medicare/Medicaid Services ("CMS") defines medical necessity as "health-care services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms that meet accepted standards of medicine."

- Who decides it?
  - Professional judgment of medical providers

    v.
  - Department of Justice ("DOJ")
  - Office of Inspector General – United States Department of Health and Human Services ("OIG-HHS")
  - Zone Project Integrity Coordinators ("ZPICs")/Medicare Administrative Coordinators ("MACs")

Criminal Allegations of Medically Unnecessary Procedures and Drugs

- Perfunctory, recurring patient visits
- Billing for procedures more costly than those actually performed
- Unnecessary ambulance transportation and falsified run sheets to conceal
- Test results ordered but not reviewed
- Unnecessary ambulance transportation and falsified run sheets to conceal
- Prescriptions for controlled substances without doctor visit
- Unnecessary compounded drugs

Civil Challenges to Medical Necessity

- MACs and ZPICs may challenge medical necessity based on:
  - "Aberrancies" in billing
  - Many similar procedures being billed
  - Duplicative coding or other coding oddities
- Varying levels of deference to physician determinations, but more likely to be challenged where no clear guidance (*e.g.,* vague LCDs)

Best Defenses

- Maintain complete and accurate patient records that are signed and dated by appropriate medical professionals;
- Individualize patient records and avoid “boilerplate” language (comes up with ERM);
- Review applicable LCDs/NCDs and incorporate medical necessity requirements into forms

Recent Enforcement Actions: Patient Quotas

Allegations of Medically Unnecessary Procedures Based on Patient Quotas

- Quotas for minimum number of services clinicians must perform (procedures, diagnostic tests, DME purchases)
  - Example: "I need 20 patients to be tested on each one this month no matter what."
- Quotas for minimum number of patients clinicians must see in a given time period
  - Example: "Bottom line every department must have a schedule of appointments that are filled for each day PREpared."
- Quotas for minimum number of patients holding a particular type of insurance
  - Example: "Goal 8 medicare/Tricare plus 8 [Workers' Compensation] a day let's get it."

Allegations of Medically Unnecessary Practices Based on Billing Targets

- Billing targets for individual patients
  - Example: Creating "pre-bills" to meet targets (*i.e.*, preparing patient bills prior to the appointment)
  - Example: "Just remember in the dx tests the total of them all must net out at 2k. You will have to add an additional 1 or 2 dx tests to meet this goal. Xray net goal $800."
- Establishing targets for number of patient visits
  - Example: "PT visit goals is for 3 PT visits per week … revenue goal for PT + PT massage patients: $2,000,000."
- Establishing scheduling policies designed to fill clinicians' schedules irrespective of medical necessity
  - Example: "No one has called any patients to fill empty slots in provider schedules…"

Best Practices

- Avoid policies that require clinicians to meet specific quotas or goals with respect to the number of patients seen or number of tests/referrals ordered.
- Exercise caution when drafting policies that even encourage clinicians to see a high volume of patients and/or maintain a full schedule.
- Policies that address patient/referral volume should emphasize medical necessity above all else (including volume).
- Clinicians should be trained and monitored to ensure their medical notes satisfy medical necessity criteria for all services or procedures ordered.

Recent Enforcement Actions: Opioid Diversion

Increased Enforcement Focus on Opioids

- Top priority of the Department of Justice
- Criminal prosecutions of healthcare professionals
  - Violations of Controlled Substances Act
  - Diversion/Tampering with controlled substances
- Civil penalties for violations of the Controlled Substances Act
  - Failure to provide effective controls and procedures to guard against theft or diversion of controlled substances;
  - Failure to report theft or diversion in timely manner
  - Failure to maintain complete and accurate records and inventories of all controlled substances

Targets of Enforcement Efforts

- Active enforcement efforts against:
  - Opioid manufacturers
  - Pharmacies
  - Hospitals
- Potential liability for all in opioid distribution stream
- Investigations often stem from reports of diversion by one or two employees
  - Expand to review of compliance with DEA administrative and record keeping requirements
  - DEA often finds lax oversight of opioid dispensing and purchasing in hospitals

Pharmacy Settlements

Date	Entity	District	Amount
April 2013	CVS	W.D. Ok.	$11,000,000
June 2013	Walgreens	S.D. Fl.	$80,000,000
May 2015	CVS	M.D. Fl.	$22,000,000
February 2016	CVS	D. Md.	$8,000,000
March 2017	Rite Aid	C.D. Ca.	$834,200
July 2017	CVS	E.D. Ca.	$5,000,000
June 2018	CVS	E.D.N.Y.	$1,500,000

Manufacturer/Distributor Settlements

Date	Entity	District	Amount
January 2017	McKesson	Nationwide	$150,000,000
July 2017	Mallinckrodt	Nationwide	$35,000,000

Hospital Settlements

Date	Entity	District	Amount
July 2014	Dignity Health	N.D. Ca.	$1,550,000
September 2015	Massachusetts General Hospital	D. Mass.	$2,300,000
September 2016	Tufts Medical Center	D. Mass.	$100,000
December 2016	Rideout Health	N.D. Ca.	$2,425,000
May 2018	Effingham Health System	S.D. Ga.	$4,100,000
May 2018	Nantucket Cottage Hospital	D. Mass.	$50,000
August 2018	University of Michigan Health System	E.D. Mi.	$4,300,000

Consequences of Civil CSA Settlements

- Huge fines
- Reputational harm
- Collateral consequences
  - Patient harm can result in lawsuits
- Bottom line: Every individual and company in the supply chain of controlled substances – manufacturers, distributors, pharmacies, hospitals, and medical practices – must be aware of DEA's intricate record keeping requirements and must be cognizant of the enforcement risks in this area.

How to Minimize Risk

- Establish strong diversion detection/prevention program
  - Diversion Specialist
  - Diversion Response Team
  - Diversion Oversight Committee

- Continually monitor and assess strength of program
  - How strong is it?
  - What systems do you have in place?
  - When did you last update your system?
  - If any potential concerns about strength of program, retain counsel to evaluate and assess under umbrella of privilege.

How to Minimize Risk (cont'd)

- If you suspect or learn of theft/diversion by employee:
  - Obligation to report "significant losses" to DEA within one day
  - Immediately conduct internal investigation
    - Evaluate with counsel reporting obligations and whether to self-report
  - Prompt action shows good faith and can help reduce damages in government investigation/resolution

Recent Enforcement Actions: Use of the Travel Act in Healthcare Fraud and Abuse Cases

What is the Travel Act?

- Federal criminal statute: 18 U.S.C. § 1952
  - Dates back to Kennedy administration
  - Enacted in 1961 as a tool to combat racketeering
    - *E.g.*, illegal gambling, illegal liquor production, prostitution, distribution of drugs, and bribery of public offices (usually by organized crime)
- To establish a violation of the Travel Act, the government must prove three elements:
  1. A defendant traveled in interstate commerce or used the mail or any facility in interstate commerce;
  2. A defendant intended to promote, manage, establish, carry on, or distribute the proceeds of illegal activity; and
  3. A defendant willfully committed an act in furtherance of that intent (element #2) after the act of travel (element #1).

Travel Act and Healthcare Fraud

- Why use the Travel Act to prosecute healthcare fraud?
  - Means of prosecuting health care fraud that does not affect federal government payors (e.g., private insurance payors)
  - Establish federal jurisdiction where the activity in question is only a violation of state law
- Recent Examples:
  - *US v. Payne,* 18-CR-00053 (C.D. Cal): Alleging that a hospital paid kickbacks to doctors to refer workers' compensation patients for surgery in violation of the California Business & Professions Code and the California Insurance Code.
  - *US v. Snyder, et al*, 18-CR-80111 (S.D. Fl.): Alleging that a sober home and its principals ordered medically unnecessary tests and paid kickbacks in return for patient referrals in violation of the Florida Patient Brokering Act.
  - *US v. Beauchamp, et al.,* 16-cr-0516D (N.D. Tex. Nov. 16, 2016): Alleging that a physician-owned hospital paid bribes to surgeons in exchange for patient referrals in violation of the Texas Commercial Bribery Statute.

Unsuccessful Defenses to Use of Travel Act in Healthcare Fraud Cases

- Preemption by federal laws
  - *USA v. Barker, et al.*, 16-CR-516-D (N.D. Tex.): Holding the Federal Anti-Kickback Statute (AKS) did not preempt a Travel Act claim based on Texas state law because Congress did not make the AKS the exclusive means for prosecuting healthcare fraud.
- Vagueness challenges
  - *USA v. Greenspan,* 16-CR-114-WHW (D.N.J.): Holding that a New Jersey law underlying a Travel Act claim did not fail to provide "fair warning" to physicians that bribery was unlawful where state medical board regulations explicitly prohibited such conduct.

Best Practices

- Health care providers and entities should educate themselves on all applicable state laws, including and especially those (like anti-bribery laws) that are not specific to the healthcare industry.
- Health care providers and entities should engage in the same vigilant compliance efforts when dealing with private payors as with federal government programs.
- Compliance programs must take into account applicable state laws and monitor compliance with them.

Questions & Answers

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