



Hot Compliance Issues for Physician Practices: An Ounce of Prevention

**2016 MGMA-LA Annual Conference
August 18, 2016
New Orleans, LA**

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Focus of Presentation

- FDA Investigations of physicians purchasing imported drugs
- Recent fraud settlements: anesthesia services and laboratory services for non-governmental patients
- OIG settlements based on insufficient documentation
- Recent HIPAA settlements: business associates, mobile devices, sufficient risk analysis and risk management plan



FDA Investigations of Imported Drugs and Devices

- Significant liability for physicians who purchased imported, non-FDA approved drugs and administered or dispensed to their patients.
- FDA warning letters – **Do Not Ignore!**
- Recent example of warning letters and cases related to orthovisc and synvisc purchased from or through Canada and Turkey.

Stay Alert!





FDA Investigations/ Settlements

- Tennessee and Virginia orthopedic practices paid \$1.85 million to settle allegations of violating the False Claims Act for knowingly billing for non-FDA approved orthovisc and synvisc.
- Ohio oncologists (Jan. 2014) paid \$2.6 million after pleading guilty to purchasing and using non-FDA approved drugs from Canada.
- Rheumatologist (August 2014) paid \$650,000 in restitution after pleading guilty from causing the shipment of boniva, prolia, euflexa and orthovisc from outside the U.S.



Non-FDA Approved Drugs and Devices: Legal Issues

- Causing the shipment of misbranded drugs is a misdemeanor under the Food, Drug and Cosmetic Act
- A drug may be considered misbranded even it is determined to be identical in composition to a FDA approved drug by the same manufacturer.
- Refund obligations and False Claims Act liability because non-FDA drugs are not covered by Medicare.



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FDA Issues: Compliance Steps

- LSBME – The Drug Supply Chain Security Act, as of Jan. 1, 2015, requires all healthcare providers to purchase their prescription drug products from authorized trading partners licensed by or registered with the state or federal government.
- Health care providers can check with the Louisiana Board of Wholesale Drug Distributors to verify that a vendor is licensed to sell drugs or devices.
- Check the packaging for: instructions in a foreign language or post-marked by a foreign country; language limiting use to prescription only; FDA-approved labeling, including “Rx only” symbol.



Investigations related to Anesthesia and Lab Services





Anesthesia Service Agreements

- OIG Advisory Opinion on “Company Model” to provide anesthesia to ASCs through a physician-owned subsidiary.
- Sweet Dreams Nurse Anesthesia
 - (August 2016) Paid \$1,034,416 to settle allegations of paying kickbacks to ASCs for exclusive agreements
 - Provided free anesthesia drugs to ASCs
 - Funded construction of an ASC



STOP

STOP

FEDERAL RESERVE NOTE
HB 624

ONE HUNDRED
HB 62411510
Secretary of the Treasury



IN GOD WE TRUST

AND STAMPS ON

50

U.S. CAPITOL



Fraud Investigations of Laboratory Services Agreements

- Significant trend of Federal investigations of lab companies and health insurance lawsuits against lab companies.
- Allegations include paying remuneration to physicians for patient referrals and billing federal health care programs for medically unnecessary tests.
- BioDiagnostic Laboratory Services settlement: offering bribes and accepting inducements to physicians.
- Sigulex Laboratories settlement: based on paying inducement to physicians.

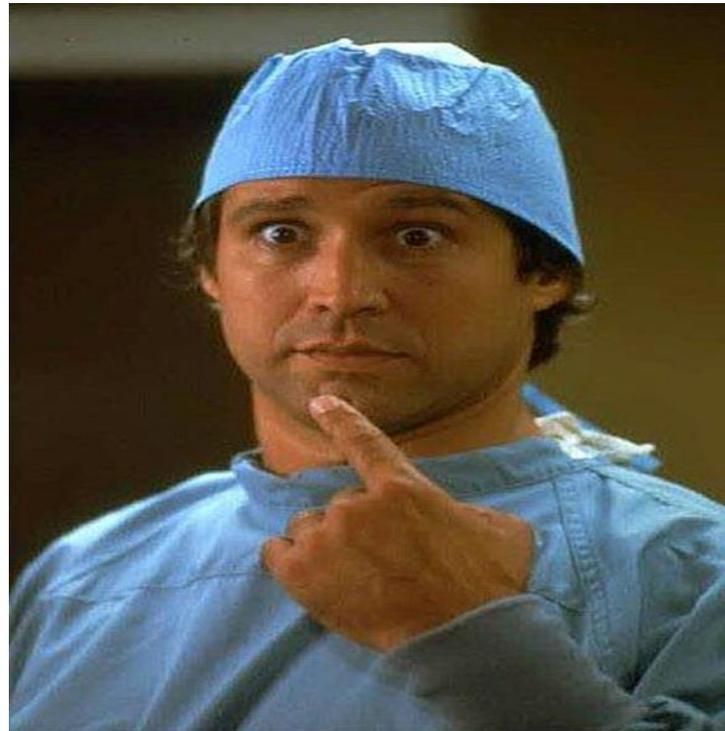


Laboratory Services Fraud Cases

- **Millennium Health, LLC settlement:** Paid \$250 million to settle false claims act allegations based on alleged kickbacks to physicians.
- **Regional Medical Laboratory (May 2016)** – Paid \$1,095,000 to settle allegations of violating the civil monetary penalties law provisions on kickbacks and self-referrals for remuneration paid to physicians in the form of a profit splitting arrangement related to lab services for ***non-governmental business.***



Fraud Settlements Based on Insufficient Documentation





Fraud Settlements Based on Insufficient Documentation

- Several recent settlements based in part on insufficient or no medical record documentation.
- Civil monetary penalty law provisions related to false claims.
- Concerns with billing for services with “incomplete” or “insufficient” documentation by the performing physician (e.g., Open / Incomplete Electronic Medical Records).



Questions?

