OBER | KALER
Attorneys at Law

Pricing Issues Affecting Laboratories

S. Craig Holden, Esquire
Ober | Kaler, A Professional Corporation
100 Light Street
Baltimore, Maryland 21202
(410) 685-1120

Fraud and Abuse Authorities

- Statutorily regulated areas of conduct
  - Claims for reimbursement
  - Relationships with referral sources

Civil False Claims Act

- Prohibits
  - filing, or causing to be filed
  - “false or fraudulent” claims
  - Using false statement to “conceal, avoid or decrease” a government obligation
- Intent
  - “Intent to defraud” not required
  - Filing claims with “reckless disregard” of their truth or falsity is sufficient
    - “Honest mistakes”

Civil False Claims Act

- Liability
  - 3X Damages
  - $5,500 to $11,000 *per claim*

Civil False Claims Act

- *Qui Tam* Provisions
  - "private attorney generals"
  - Can proceed even if Government declines
  - Can receive up to 30% of recovery
- State FCAs

Federal Anti-Kickback Statute

- Prohibited Conduct
  - Knowing & willful
    - Solicitation or receipt *or*
    - Offer or payment of
  - Remuneration
    - In return for referring a Program patient, *or*
    - To induce the purchasing, leasing , *or* arranging for or recommending, purchasing or leasing items or services paid by Program

Federal Anti-Kickback Statute

- Penalties
  - Criminal fines & imprisonment
  - Civil money penalty of $50,000 *plus* 3X the amount of the remuneration
  - Exclusion
  - False Claims Act liability

Intent:ACA

- Section 6402 (f) (2)
  - "With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section."
  - Legislatively overrules *Hanlester*

Federal Anti-Kickback Statute

- Statutory Exceptions
  - Discounts
  - Bona fide employment relationships
  - GPO fees
  - Certain co-payment waivers
  - Certain managed care arrangements
- Regulatory Safe Harbors
- Advisory Opinions
  - Posted on OIG Website
    - www.hhs.gov/oig

Discounts

- Discount safe harbor
  - 3 buyer categories
    - Cost-report
    - HMO/CMP
    - Other
  - Disclosure of discounts

Discounts

- ***Not*** a discount
  - Cash or cash equivalents
  - Discounts on one item based on purchases of a different item
  - Reductions in price to one payer but not Medicare/Medicaid
  - Waivers of co-pay/deductible

Discounts

- "Swapping"
  - Advisory Opinion 99-2
    - Discount arrangement between Ambulance Company and SNF for PPS and non-PPS transports
  - Advisory Opinion 99-13
    - Discount arrangement between Pathology Group and Hospitals or Physicians

Discounts

- OIG Indicia of "Suspect" Discounts
  - Discounted prices below fully loaded (not marginal) costs
  - Discounted prices below those given to buyers with comparable "account" volume, but without potential Program referrals

Discounts

- Subsequent Retreat
  - Discounts below fully loaded costs not *per se* unlawful
  - Must be a “linkage” between the discount and referrals of Program business

    Letter of Kevin G. McAnaney,
    OIG Industry Guidance Branch (April 26,2000)

Discounts

- Compliance Guidance for Clinical Laboratories
  - 63 Federal Register 45,076 (August 24,1998)
    - Uses “fair market value” concept
  - Advisory Opinion 11-11 reiterates “below cost” theory of “swapping”
    - No discussion of fully-loaded vs. marginal costs
- Stark Exception for payments by physicians
  - Fair market value not required for clinical laboratory services
  - Fair market value required for all other services

Recent Enforcement Activity

- *U.S. and California ex rel. Pasqua v. Kan-Di-Ki, LLP et al, dba Diagnostic Laboratories and Radiology*.
  - Government alleged that clinical lab/mobile x-ray company gave kickbacks in the form of below-cost discounted pricing to nursing homes on client-billed work to induce Medicare Part B referrals
  - False Claims Act allegations settled for $17.5 million in September, 2013

Recent Case Law

- Courts have not been receptive to the Government's swapping theories
  - *Klaczak v. Consolidated Med. Transp.*, 458 F. Supp. 2d 622, 678-80 (N.D. Ill. 2006), ("a discount compared to what?")
  - *U.S. ex rel. Jamison v. McKesson Corp.*, No. 2:08cv214-SA-JMV, (2012)
  - *U.S. ex rel. Obert-Hong v. Advocate Health Care*, 211 F. Supp. 2d 1045, 1047 (N.D. Ill. 2002)

“Substantially in Excess”

- May not bill Medicare “substantially in excess” of “usual” charge
  - Basis for exclusion
  - 1972 version referred to “customary” charge
- No enforcement activity since law passed in 1972

“Substantially in Excess” (Cont’d)

- 1990 Proposed Rule
- 1992 Final Rule
- 1997 Proposed Rule
- 1998 Withdrawal
- 2001 False Alarm

“Substantially in Excess” (Cont’d)

- Proposed Rule (9/2003)
  - “Substantially in excess” defined as 120% of “usual charge”
    - Good cause exception
  - “Usual charge” defined as mean of all charges (median also being considered)
    - Includes contractual rates , even if billed at list
    - Excludes capitated and other comparable rates
    - Excludes federal payor rates
- Rule withdrawn (6/2007)

Protecting Access to Medicare Act of 2014

- New federal price reporting obligations
  - Who: All clinical laboratories with >50% of revenues from clinical lab testing
    - Possible carve-out for small labs

Protecting Access to Medicare Act of 2014

- New federal price reporting obligations
  - What: Test-by-test data showing the price ***paid*** by all all “private payers”
    - “Private payers” include health insures, group health plans, Medicare Advantage plans and Medicaid managed care plans
    - Reported prices must be net of all discounts, rebates, etc.
      - Capitated pricing not to be reported

Protecting Access to Medicare Act of 2014

- New federal price reporting obligations
  - When: Every 3 years starting January 1, 2016
  - CMP of up to $10,000 per day for failure to report or false reports
  - Regulations must be issued by June 30, 2015

Protecting Access to Medicare Act of 2014

- New federal price reporting obligations
  - Why: Medicare reimbursement will be set at the weighted median of the reported prices per test starting January 1, 2017 and stay in effect until the next reporting period
    - Reductions phased in
      - Initial reductions capped at 10%
      - Later period reductions capped at 15%
    - Special rules for new tests

Protecting Access to Medicare Act of 2014

- New federal price reporting obligations
  - Key points
    - Client pricing *not* implicated
    - Unclear how pricing of components of tests priced on a bundled basis will be reported
    - Unclear if reporting be limited to payers with material volume

State Law Issues

- Medicaid pricing limitations-various state laws
  - Most states simply require providers to bill at “usual and customary” rates
  - Massachusetts
    - “Usual and customary” is defined as the lowest fee in effect at the time of service that is charged by the lab for any service.
      – Mass. Regs. Code tit. 130, § 401.402

State Law Issues

- Medicaid pricing limitations-various state laws
  - California
    - "Notwithstanding any other provisions of these regulations, no provider shall charge for any service… more than would have been charged for the same service… to other purchasers of *comparable services*… under *comparable circumstances*."
      - – 22 CCR § 51501(a)(emphasis added)
    - Suspended as to laboratories by AB 82

State Law Issues

- Medicaid pricing limitations-various state laws
  - Florida: "Charges" to Florida Medicaid may not exceed "the provider's lowest *charge* to any other third party payment source for the same or equivalent medical and allied care, goods, or services . . . ." *Fla. Admin. Code r. 59G-5.110(2)*
  - Lowest charge regulation and related Manual provisions stricken by ALJ as contrary to statute and thus exceeding the Agency's authority Case No. 14-0010RX

State Law Enforcement

- State litigation
  - *California ex rel. Hunter Laboratories v. Quest Diagnostics, et al.*
    - Allegations
      - – Violations of Sec. 51501
      - – Pricing “kickbacks”
        - IPA capitated pricing
        - FQHC pricing
          - FQHC Safe Harbor

State Law Enforcement

- California settlements
  - Qui tam suit
    - Quest Diagnostics--$241 million
    - LabCorp--$49.5 million
    - Other settlements
  - DHCS Audit activity
    - Numerous settlements

State Law Enforcement

- Actions pending in other States
  - Georgia (State declined)
  - Florida (State intervened)
  - Nevada (State declined)
  - Massachusetts (Commonwealth declined)
  - Michigan (State intervened)
  - Virginia (Commonwealth declined) (Case dismissed)

Pricing Rules of Thumb

- Never tie client pricing to referrals of Medicare/Medicaid work
- Try to ensure that client bill pricing is profitable on a stand-alone basis, at least on a marginal cost basis
- Be cognizant of pricing patterns across clients

QUESTIONS?