

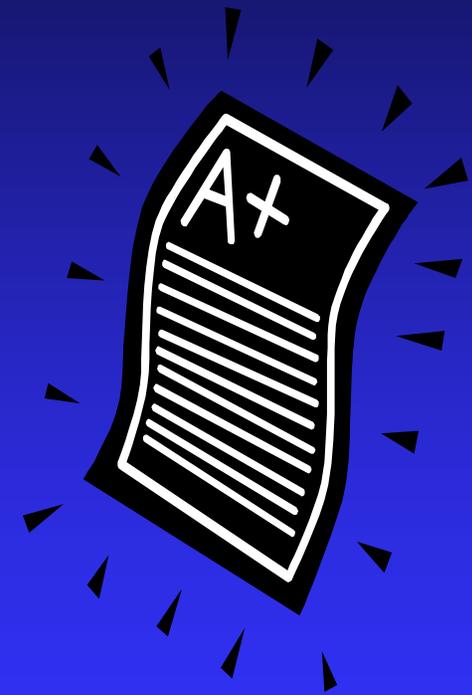


**MEDICARE MYTHS
AND REFORMS:
Proactive Strategies for
Protecting Physicians
and Medicare Physician
Benefits**

Amy L. Woodhall, Walter & Haverfield, LLP

How are Health Care Providers and Physicians Doing?

- 6.3% improper payments for 2001
 - ◆ 1/2 1996 error rate
 - ◆ 42.9% Documentation
 - ◆ 30.5% Insufficient
 - ◆ 12.4% None
 - ◆ 43.2% Medical Necessity
 - ◆ Primarily I/P
 - ◆ 17.0% Coding Errors



How are Carriers Doing?

- 2001-02 GAO Reports
 - ◆ 53% carrier responses incomplete
 - ◆ 32% entirely inaccurate
 - ◆ 15% accurate and complete



14 Medicare contractors convicted, fined or settled since 1993

- ◆ Improper processing and payment of claims to receive more than justified payment
- ◆ Destroying claims to eliminate backlogs
- ◆ Not collecting overpayments and attempting to conceal via false records
- ◆ Falsifying performance documentation and reports
- ◆ Altering/hiding files of incorrectly processed or paid claims
- ◆ Conspiring to obstruct federal audit

The Good News

- A physician and his wife convicted of mail fraud were granted new trial on basis of trial testimony by Medicaid auditor that district court found was “false to a dramatic degree.”

U.S. v. Mitrione



- If truth or falsity of statement centers on legal interpretation, gov't must prove beyond reasonable doubt statement is not reasonable interpretation of law

U.S. v. Whiteside



“Tainted Claims” Theories

Claim “false” only if MD certifies compliance with law or rule *that is condition to government payment.*

Implied false certification viable only if underlying rule states compliance is prerequisite to payment.

Mikes v. Strauss

AKB can be predicate act for FCA,

- ◆ But must plead and prove gov’t. would have refused payment if it had known
- ◆ Bootstrapped antikickback claims require same burden of proof (criminal intent) under FCA.

US ex rel. Sharp v. Consolidated Medical Transport

EMTALA

- **Not a federal standard of care or remedy for inadequate or inaccurate diagnosis.**
 - ◆ *Phillips v. Hillcrest Medical Center*
- Private cause of action applies to participating hospitals, not individual MDs.
 - ◆ *Nelson v. Calvin* (D. Kan. 2001)



Proposed EMTALA Rule on Availability of On-call Physicians

- Hospital must maintain an on-call list of physicians in manner that best meets needs of hospital's patients.
- **Physicians, including specialists and subspecialists, are not required to be on call at all times.**
- Hospital must have written policies and procedures in place to respond to situations in which
 - ◆ A particular specialty is not available or
 - ◆ On-call physician cannot respond because of circumstances beyond physician's control.

(May 9, 2002)

FCA \$11,000/Claim & Treble Damages

- Subject to case-by-case analysis under Excessive Fines Clause of 8th Amendment.
- District court ordered to determine whether \$550,000 fine and \$174,454 in treble damages for \$58,151 in Medicare overpayments unconstitutionally excessive.

U.S. v. Mackby (9th Cir. 2001)



The Bad News



Pretrial detainee may be forcibly injected with antipsychotic medication for sole purpose of being competent to stand trial without violating Due Process rights.

U.S. v. Sell

Govt. need not allege monetary damages to state FCA claim.

Varljen v. Cleveland Gear Co and Wilentz, Goldman & Spitzer

Broad HIPAA Subpoena Power



- Documents which “may be relevant to an authorized law enforcement inquiry involving federal health care offense.”
 - ◆ Professional magazines received containing billing and coding compliance advice, financial records of minor children
In re Administrative Subpoena, John Doe v. U.S
 - ◆ Relevant hospital credentials files
United States v. United Mem. Hosp.
- Does Immunity for producing documents override medical record privacy?

New Theories to Watch: Conspiracy

- (1998) Conviction of Pain Mgmt. Physician
- (2001) Michigan hospital charged with mail & wire fraud
 - ◆ Billing facility fee for physician's medically unnecessary procedures.
 - ◆ 2,400 pain procedures, "1/3 of bottom line"





Conspiracy Theory

Physicians, *in their capacity as leaders* of medical staff, indicted on conspiracy charges

- Participated in conspiracy by failing to supervise, stifling criticism and investigations, manipulating peer review process
- No federal peer review privilege over credentials files

U.S. v. United Memorial Hospital

Rx Fraud and Abuse

PDMA and kickback allegations bring record \$875M settlement from TAP

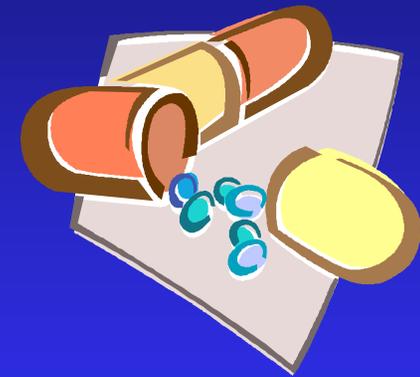
- ◆ conspiring with doctors to charge Medicare and Medicaid for free samples
- ◆ paying kickbacks to doctors (Aspen, Captiva Island) for dispensing Lupron
- ◆ Offering Tufts educational grants to take Zolodex off formulary



- PhRMA
Voluntary Code
- AMA
- OIG

Pharmaceutical Fraud and Abuse

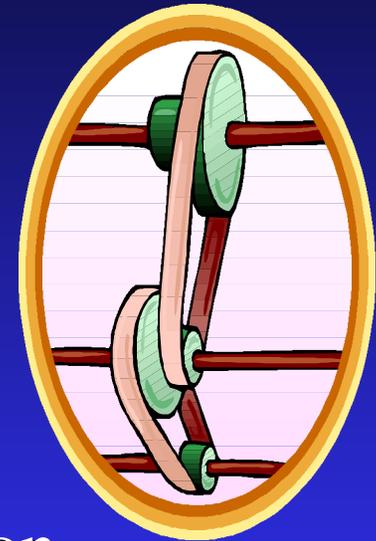
- **Criminal Prosecutions for Oxycontin deaths (racketeering and manslaughter)**
- **Online Prescribing without Exam**
- **Sales Without Prescriptions**



MEDICARE REFORMS – BACKLASH

- ◆ BIPA Reforms
 - ◆ NCD/LMRP appeals
 - ◆ Claims Appeals

- ◆ HHS Advisory Committee on Regulatory Reform
 - ◆ Recommends eliminating E&M Guidelines



Mead/Christiansen – 2000-01

- Some erosion of extremely deferential approach to agency interpretations of statute
- Formal rules via notice-and-comment rule making entitled to judicial deference.
- Informal interpretations lack force of law and do not warrant judicial deference
 - ◆ policy statements, agency manuals, and enforcement guidelines



Test for Informal Positions = Whether Power to Persuade?

- Factors
 - ◆ Thoroughness
 - ◆ Validity
 - ◆ Consistency
 - ◆ Persuasiveness
- Lack of any sound basis behind policy

U.S. Freightways Corp. v. IRS
- Inconsistent with ordinary meaning of statutory text

Catskill Mountains v. City of New York

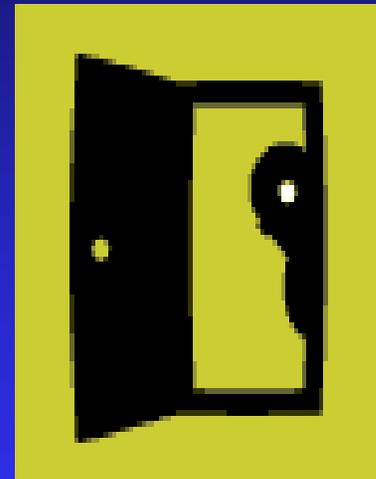


Medicare Preclusion/Exhaustion of Remedies

- *Allstar Care Inc. v. BCBS of So. Carolina*
 - ◆ Court dismissed claims of Florida provider against Medicare intermediary for consistently denying claims, alleging tortious conduct to drive provider out of business.
 - ◆ Alleged harm – suspending payments, denying claims, and performing audits – are functions that Congress authorized intermediary to perform.

Medicare Preclusion Exhaustion of Remedies

- Growing line of cases allow exception considering two factors:
 - ◆ Inability to access administrative review
 - ◆ Severity of penalty in event of noncompliance



MEDICARE MYTHS Medical Necessity

“Not reasonable and necessary for dx and treatment of illness or injury or to improve functioning of malformed body member”



Financial Liability Protections

- ◆ Limitation of Liability and Refund Waiver
- ◆ Advanced Beneficiary Notices (ABNs)

Advanced Beneficiary Notices (ABNs)

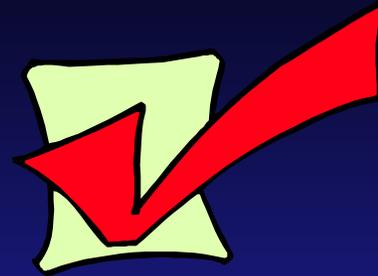
- Assigned Claims
 - ◆ Beneficiary properly notified
 - ◆ No explicit requirement for agree to pay but ABN form includes language “as a matter of full disclosure.”
 - ◆ Can document refusal to sign and submit with GA modifier

- Unassigned Claims
 - ◆ Unassigned claim refund waiver requires both notice and beneficiary agreement to be liable.



CMS Program Memorandum Transmittal AB-02-114
(July 31, 2002) effective Oct. 1, 2002

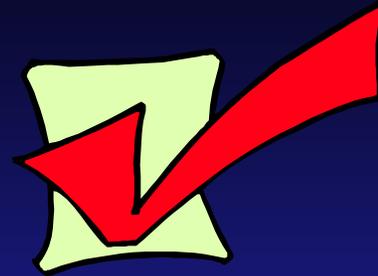
ABN Forms



CMS-R-131 G (General) L (Lab)

- Customize Header, Items or Services, and Because boxes
 - ◆ Check off boxes ok, but must be one page
- Timely delivery allows meaningful opportunity to act (before procedure initiated, no anesthesia)
- Authorized representative if coma, confused, incompetent, duress, language barriers

ABN Forms

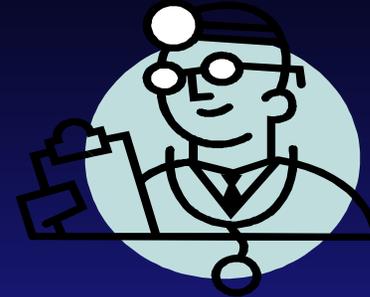


- Should not be given if EMTALA applies until
 - ◆ Medical screening exam completed
 - ◆ Emergency medical condition stabilized
- Use of Modifiers
 - ◆ GY – Statutory exclusion
 - ◆ GA – Expect denial – ABN on file
 - ◆ GZ – Expect denial – no ABN

Routine ABNs

- Rule says ABN not acceptable if “physician routinely gives this notice to ALL beneficiaries for whom he or she furnishes services.” 42CFR 411.408(f)(2)(i)
- HHS argued in *United Seniors Assn v. Shalala* that rule for doctors who “require ALL patients to sign ABNs on blanket basis in order to bill them for unwarranted procedures.”
- Court held that therefore HHS does not interpret ABN procedures to deny plaintiffs access to medically necessary services
- “If plaintiffs feel HHS enforces ABN statute and regs in manner inconsistent with its own pronouncements, they are free to challenge such enforcement in a particular case.”

Routine ABNs



- CMP for pattern of medically unnecessary services. HIPAA §231(e)(4)
- HIPAA Conference Report
 - ◆ No sanction intended for providers who simply inform beneficiaries that Medicare does not cover a particular service
- CMS ABN Prog. Memo
 - ◆ HIPAA deals with fraudulent claims for patently unnecessary medical care
 - ◆ ABNs deal with likelihood that Medicare may deny as medically unnecessary

Routine ABNs: No Specific Reason

- “Routine” use of ABNs is “not effective”
 - ◆ Generic ABNs (“Possible,” “Never Know”)
 - ◆ Blanket ABNs for all items and services
 - ◆ Signed Blank ABNs
- Exceptions
 - ◆ Services are always denied under NCD
 - ◆ Experimental (not proven safe and effective)
 - ◆ Exceeds frequency limit in law or LMRP

CMS Program Memorandum Transmittal AB-02-114

Limitation of Liability and Refund

- Physician financially liable if fails to provide proper ABN where required, unless physician can show
 - ◆ that he or she did not know and could not reasonably have been expected to know Medicare would deny payment

ABN Charges



- No Medicare limit on amount collected
- Lack of amount on estimated cost line or amount different from final actual cost does not invalidate ABN
- But matter between physician and patient, advisable to estimate

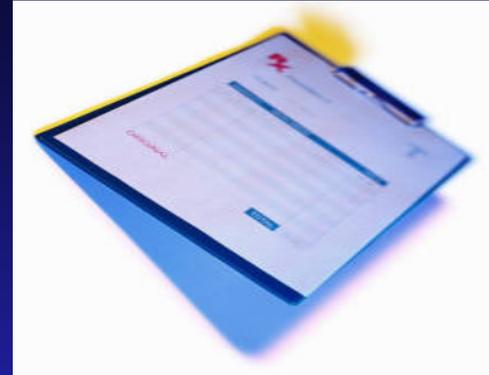
Coding Issues 42 C.F.R. §405.512

- “Procedural terminology and coding systems provide physicians and third party payors with *common language* to accurately describe kinds and levels of services provided and covered.”
 - ◆ Rule sets forth procedures and guidelines for carrier request and approval for its coding system.



Coding

- (1990) Physicians must use standard claim form
 - ◆ Instead of creating new coding system for physician services, HHS contracted with AMA to “adopt and use” CPT.
- CMP for pattern or practice of upcoding
- (1998) Medicare payment denials and CMPs for failing to provide “appropriate diagnosis code”



- (2002-03) HIPAA code set rule adopted CPT-4 for physician services electronically billed by covered entities.

Without Fault Rule

- No overpayment liability for incorrect Medicare payment if
 - ◆ Without fault, and
 - ◆ Adjustment or recovery would:
 - ◆ Defeat the purposes of the Medicare benefit, or
 - ◆ Be against equity and good conscience.



Without Fault Rules: E&M

- “Due to complexity of coding and trying to determine for example, whether history was detailed, comprehensive, and so forth, it is determination of undersigned to waive any perceived overpayment based on coding of examination in this case.
- Physician exercised *reasonable care and due diligence* in billing at levels initially coded in these cases. Additionally, physician had *reasonable basis* for level billed and for accepting payment made under these codes.
- Consequently, I find that physician was and is without fault.”

Lack of Code for Physician Services

- Is a medical procedure “experimental” until such time as a CPT code is developed?
 - ◆ Not if physician benefit
 - ◆ Reasonable and necessary, and
 - ◆ Reasonable basis for code selection

Congressional Reforms Necessary

- CMS guidance and outreach
 - ◆ Clarity, predictability, simplicity
- Audits
 - ◆ Random audits, extrapolations, settlements, repayment plans
- Rulemaking
 - ◆ Retroactivity and opportunity for comment
- Appeals
 - ◆ BIPA oversight, ALJ cadre judges
- Medicare contractor reform
 - ◆ Competitive contracting, performance and accountability, limit liability if due care
- Protection for reliance on written carrier guidance

