

# Making Sense of the Medicare Manuals

Presented by:

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**Fredrikson**  
& BYRON, P.A.



# What's Old Is New Again?

- Investigational Device case from the 1990s: Cedars-Sinai Medical Center v. Shalala, 177 F.3d 1126 (9th Cir. 1999) et al.
- Manual provision issued in 1986 enforced in 1994.
- The government's arguments seem surprisingly unfair.

# Don't Believe Anything I Say...

- “[The Manual] embodies a policy that itself is not even binding in agency adjudications.... Manual provisions concerning investigational devices also ‘do not have the force and effect of law and are not accorded that weight in the adjudicatory process.’ ” Gov’t brief in Cedars-Sinai Medical Center v. Shalala.
- “Thus, if government manuals go counter to governing statutes and regulations of the highest or higher dignity, a person ‘relies on them at his peril.’ Government Brief in Saint Mary’s Hospital v. Leavitt.

# If You Could Read My Mind....

- The government argued that to challenge the validity of Manual, you had to comply with the statute of limitations under the APA.
- The Court agreed: “Here, however, it is clear that the cause of action arises under the Administrative Procedure Act to challenge the manner in which the policy was announced. As such, the cause accrued at the time of that announcement.” 177 F.3d at 1129.
- Think about this logic!!

# More Tidbits

- The government paid the claims for year.
- HCFA memo notes that nothing on the claim form called for information about device status.



# Hierarchy of Authority

- Constitution (due process, contracts clause, enumerated powers).
- Statutes (Social Security Act).
- Regulations (42 CFR).
- Program guidance (Manuals, bulletins, FAQs, regulatory preambles).

# What Are the Medicare Manuals?

- Sub-regulatory guidance.
- CMS's instructions for administration of the Medicare program.
- Examples:
  - Medicare Claims Processing Manual.
  - Medicare Benefit Policy Manual.
  - National Coverage Determinations Manual.

# Google with Caution!

The image shows a Google search interface with the query "42 cfr 410.32". The search results are as follows:

- Search:** 42 cfr 410.32
- Navigation:** All, Maps, Shopping, News, Videos, More, Settings, Tools
- Results:**
  - PDF] 42 CFR Ch. IV (10–1–03 Edition) § 410.32 - CMS.gov**  
[https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/.../410\\_32.pdf](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/.../410_32.pdf) ▼  
252. 42 CFR Ch. IV (10–1–03 Edition). § 410.32 central or peripheral) to permit monitoring of beneficiaries in the future if the initial test was performed with a.
  - 42 CFR § 410.32 - Diagnostic x-ray tests, diagnostic laboratory tests ...**  
<https://www.law.cornell.edu> > ... > Subpart B. Medical and Other Health Services ▼  
(a)Ordering diagnostic tests. All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the ...  
You've visited this page 4 times. Last visit: 8/1/19
  - 42 CFR 410.32 - Diagnostic x-ray tests, diagnostic laboratory tests ...**  
<https://www.gpo.gov/fdsys/granule/CFR-2011.../CFR-2011-title42-vol2-sec410-32> ▼  
Oct 1, 2011 - 42 CFR 410.32 - Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.  
You've visited this page 3 times. Last visit: 7/20/18
  - 42 CFR 410.32 - Diagnostic x-ray tests, diagnostic ... - GovRegs**  
[https://www.govregs.com/.../title42\\_chapterIV\\_part410\\_subpartB\\_section410.32](https://www.govregs.com/.../title42_chapterIV_part410_subpartB_section410.32) ▼  
Provides the text of the 42 CFR 410.32 - Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions. (CFR).

# Google with Caution!

[PDF] 42 CFR Ch. IV (10–1–03 Edition) § 410.32 - CMS.gov

[https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/.../410\\_32.pdf](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/.../410_32.pdf) ▼

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# Google with Caution!

## §410.32

central or peripheral) to permit monitoring of beneficiaries in the future if the initial test was performed with a technique that is different from the proposed monitoring method.

(d) *Beneficiaries who may be covered.* The following categories of beneficiaries may receive Medicare coverage for a medically necessary bone mass measurement:

(1) A woman who has been determined by the physician (or a qualified nonphysician practitioner) treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.

(2) An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.

(3) An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to 7.5 mg of prednisone, or greater, per day for more than 3 months.

(4) An individual with primary hyperparathyroidism.

(5) An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug ther-

## 42 CFR Ch. IV (10-1-03 Edition)

sonable and necessary (see §411.15(k)(1) of this chapter).

(1) *Chiropractic exception.* A physician may order an x-ray to be used by a chiropractor to demonstrate the subluxation of the spine that is the basis for a beneficiary to receive manual manipulation treatments even though the physician does not treat the beneficiary.

(2) *Mammography exception.* A physician who meets the qualification requirements for an interpreting physician under section 354 of the Public Health Service Act as provided in §410.34(a)(7) may order a diagnostic mammogram based on the findings of a screening mammogram even though the physician does not treat the beneficiary.

(3) *Application to nonphysician practitioners.* Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the

# Links to Official Versions

- Current CFR: <https://gov.ecfr.io/cgi-bin/ECFR>.
- Federal Register: <https://www.federalregister.gov/> .
- Manuals: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html?redirect=/manuals/> .

# Pay Attention to Effective Dates

## **20.1.2.1 - Cost to Charge Ratios**

**(Rev. 2111, Issued: 12-03-10, Effective: 04-01-11, Implementation: 04-04-11)**



# Time Traveling Manual

## **10 - Covered Inpatient Hospital Services Covered Under Part A** *(Rev. 234, Issued: 03-10-17, Effective: 01-01-16, Implementation: 06-12-17)*

Patients covered under hospital insurance are entitled to have payment made on their behalf for inpatient hospital services. (Inpatient hospital services do not include extended care services provided by hospitals pursuant to swing bed approvals. See Pub. [100-02, Chapter 8, §10.3, "Hospital Providers of Extended Care Services."](#)) However, both inpatient hospital and inpatient SNF benefits are provided under Part A - Hospital Insurance Benefits for the Aged and Disabled, of Title XVIII).

Additional information concerning the following topics can be found in the following chapters *of this manual*:

- [Benefit Period is found in Chapter 3](#)
- [Counting Inpatient Days is found in Chapter 3](#)
- [Lifetime reserve days is found in Chapter 5](#)
- [Related payment information is housed in the Provider Reimbursement Manual](#)

Plan must be furnished on a health insurance plan that is a qualified hospital service to

# U.S. ex rel. Dunn v. North Memorial Health

- Relator alleged that certain supervision and documentation requirements for pulmonary and cardiac rehab services had not been met.
- But the regulation creating these requirements didn't go into effect until after the relevant time period!

# Is the Manual Up-to-Date?

## Medicare Claims Processing Manual

### Chapter 3 - Inpatient Hospital Billing

Table of Contents

*(Rev. 4337, 07-18-19)*

# Are Manuals Binding?

- What does “binding” mean?
  - Can you go to jail?
  - Is there an overpayment?
  - Are the claims false?
- *Overpayment* means any funds that a person has received or retained under title XVIII of the Act to which the person, after applicable reconciliation, is not entitled under such title.”
  - 42 C.F.R. § 401.303

# The 60 Day Rule

- The duty to “report and return” an overpayment.
- Six year look back period.
- Irony? the Manuals discuss a 4 year limit on reopening.

# FCA Materiality

“The materiality standard is demanding. The False Claims Act is not “an all-purpose antifraud statute,” or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where non-compliance is minor or insubstantial.”

Escobar, 136 S. Ct. at 2003 (citations omitted)

# FCA Knowledge

- (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information.
  - 31 U.S.C. § 3729(b).

# FCA Knowledge

- FCA “does [not] reach those claims made based on reasonable but erroneous interpretations of a defendant's legal obligations.”
  - United States ex rel. Purcell v. MWI Corp., 807 F.3d 281, 288 (D.C. Cir. 2015)



**U. S. Department of Justice**

Office of the Associate Attorney General

The Associate Attorney General

Washington, D.C. 20530

January 25, 2018

MEMORANDUM FOR: HEADS OF CIVIL LITIGATING COMPONENTS  
UNITED STATES ATTORNEYS

CC: REGULATORY REFORM TASK FORCE

FROM: THE ASSOCIATE ATTORNEY GENERAL

A handwritten signature in blue ink, appearing to be "PEB".

SUBJECT: Limiting Use of Agency Guidance Documents  
In Affirmative Civil Enforcement Cases

On November 16, 2017, the Attorney General issued a memorandum (“Guidance Policy”) prohibiting Department components from issuing guidance documents that effectively bind the public without undergoing the notice-and-comment rulemaking process. Under the Guidance Policy, the Department may not issue guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch (including state, local, and tribal governments), or to create binding standards by which the Department will determine compliance with existing statutory or regulatory requirements.

The Guidance Policy also prohibits the Department from using its guidance documents to coerce regulated parties into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or lawful regulation. And when the Department issues a guidance document setting out voluntary standards, the Guidance Policy requires a clear statement that noncompliance will not in itself result in any enforcement action.

# Details Matter

- Was the claim accurate?
- Condition of payment vs. Condition of participation.
- Would the government have paid the claim absent the errors?

## Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

# **SUPREME COURT OF THE UNITED STATES**

## Syllabus

**AZAR, SECRETARY OF HEALTH AND HUMAN  
SERVICES *v.* ALLINA HEALTH SERVICES ET AL.**

**CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR  
THE DISTRICT OF COLUMBIA CIRCUIT**

No. 17–1484. Argued January 15, 2019—Decided June 3, 2019

# Azar v. Allina

- DSH payment calculation depends on calculation of the “Medicare fraction”
- Under the statute, the Medicare fraction is:

$$\frac{\textit{Part A entitled patients who are also SSI eligible}}{\textit{Part A entitled patients}}$$

- Should Medicare Part C patients be included?

# Azar v. Allina

- CMS proposed a rule in 2003 that Part C would not be included.
- In 2004, the final rule included Part C:
  - Several successful legal challenges.
- In 2014, issued a new prospective rule including Part C:
  - Multiple pending lawsuits.

# Azar v. Allina

- 2012 DSH payments.
- CMS calculated the Medicare fraction using Part C patients and put a spreadsheet of the fractions on its website.

# 42 U.S.C. § 1395hh

(a)(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing . . . the payment for services . . . under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

# 42 U.S.C. § 1395hh

- Generally requires notice and comment rulemaking (60 day notice period).
- Exceptions:
  - Statute provides for shorter notice period.
  - Statute requires implementation in less than 150 days.
  - For “good cause”.

# “Good Cause” Exception

“[W]hen the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.”

# Allina Majority (Gorsuch)

- The spreadsheet:
  - Was a statement of policy.
  - That affected a substantive legal standard governing payment for services.
- It had not been passed via notice-and-comment rulemaking.
- It had no effect.

# Allina and the Manuals

- Majority rejected the government's argument that enforcing the statute would imperil the robust Medicare Manual system:
  - “Only eight” Manual provisions have been preserved as interpretative rules.
  - No challenges to Manual provisions in the two years since the D.D.C. decision.

# Allina Dissent (Breyer)

- Would have applied the APA's exception for interpretative rules.
- Policy concern about how the Manual system would fare under the majority's decision.

# Allina Dissent

- “[T]ens of thousands” of pages of Manual provisions.
- Handy bulletin point list of the eight portions of the Provider Reimbursement Manual that courts have treated as interpretative.

# An Important Caveat

- The Court didn't address whether the plain language of the statute creating the Medicare fraction controlled!
  - The government didn't make this (pretty good) argument:
    - Part C patients are by definition “entitled to benefits under” Part A.
- CMS could still protect Manual provisions if they are merely gap-fillers.

# Interpretive Rules vs. Gap-Filler

- Gap-filler:
  - Does not “establish or change a substantive legal standard” affecting payment.
- Interpretive rule:
  - Explains the agency’s interpretation of a statute or regulation.
  - Does not have the “force of law”.

# Two Examples

- Physician signatures.
- Concurrent surgeries.

# Physician Signatures

- Statutory requirement: None.
- Regulatory requirement: None.
- Subregulatory guidance: Inconsistent.  
No clear requirement of a signature,  
and explicit permission for attestation  
if missing.

# Program Integrity Manual, CMS Pub 100-08 § 3.3.2.4

If the signature is missing from an order, MACs and CERT shall disregard the order during the review of the claim (e.g., the reviewer will proceed as if the order was not received).

**If the signature is missing from any other medical documentation (other than an order), MACs and CERT shall accept a signature attestation from the author of the medical record entry. (bold added).**

# Contradictory Preamble

“Some commenters have requested the rationale for requiring specific written orders for tests performed by IDTFs while not imposing the same requirement on testing in physicians’ offices. The rationale for requiring testing by IDTFs to be ordered in writing by the treating physician is based in our (and, more specifically, HCFA’s contractors’) experience with IPLs.”

62 F.R. 59048, 59072 (October 31, 1997).

# CERT Request Text

Request a signature log or an attestation of medical record entries if the medical record documentation is not signed or if the signature(s) are not clearly legible. In order to be considered valid for Medicare medical review purposes, an attestation statement must be signed and dated by the author of the medical record entry and must contain sufficient information to identify the beneficiary.

# Concurrent Surgeries

At a teaching hospital, a surgeon is working with residents on three cases. One of the cases is being opened, one is being closed, and the third is in a key portion. The teaching physician was in the third case. Someone notes the following Manual language and believes fraud has been committed.

# Medicare Claims Processing Manual

## § 100.1.2 - Surgical Procedures

### 2. Two Overlapping Surgeries

In order to bill Medicare for two overlapping surgeries, the teaching surgeon must be present during the critical or key portions of both operations. Therefore, the critical or key portions may not take place at the same time. When all of the key portions of the initial procedure have been completed, the teaching surgeon may begin to become involved in a second procedure. The teaching surgeon must personally document in the medical record that he/she was physically present during the

# Medicare Claims Processing Manual

## § 100.1.2 - Surgical Procedures

critical or key portion(s) of both procedures. When a teaching physician is not present during non-critical or non-key portions of the procedure and is participating in another surgical procedure, he/she must arrange for another qualified surgeon to immediately assist the resident in the other case should the need arise. **In the case of three concurrent surgical procedures, the role of the teaching surgeon (but not anesthesiologist) in each of the cases is classified as a supervisory service to the hospital rather than a physician service to an individual patient and is not payable under the physician fee schedule.**

# Medicare Claims Processing Manual

## § 100.1.2 - Surgical Procedures

### A. Surgery (Including Endoscopic Operations)

The teaching surgeon is responsible for the preoperative, operative, and postoperative care of the beneficiary. **The teaching physician's presence is not required during the opening and closing of the surgical field unless these activities are considered to be critical or key portions of the procedure.** The teaching surgeon determines which postoperative visits are considered key or critical and require his or her presence. . .

# 42 C.F.R. § 415.172

(a) **General rule** If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought.

(1) In the case of surgical, high-risk, or other complex procedures, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure.

# 42 C.F.R. § 415.172

**(i) In the case of surgery, the teaching physician's presence is not required during opening and closing of the surgical field.**

(ii) In the case of procedures performed through an endoscope, the teaching physician must be present during the entire viewing.

# So, What Good Are the Manuals?

- “Gap fillers” potentially entitled to judicial deference.
- Risk management.
- Safe harbor?

# Judicial Deference

- “Gap filling” Manual provisions probably survive Allina.
- But how much deference would they get?

# Judicial Deference

- Deference under Auer and Kisor:
  - Regulation must be “genuinely ambiguous” even after “exhaust[ing] all the ‘traditional tools’ of interpretation” including “text, structure and history.”
  - Interpretation must be reasonable.
  - Must be a “fair and considered judgment” not a “post hoc rationalization” or a “convenient litigating position.”
  - Must not create an “unfair surprise.”

# Judicial Deference

- Deference under Skidmore
  - “We consider that the rulings, interpretations, and opinions of the Administrator under this Act, while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.”

# Manuals/Guidance Can't Limit Coverage

42 U.S.C. § 1395hh(a)(1) says nothing other than an NCD may change benefits unless promulgated as a regulation.

# 42 U.S.C. § 1395hh

(a)(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing . . . the payment for services . . . under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

# NCDs Are Complicated

Where an item, service, etc. is stated to be covered, but such coverage is explicitly limited to specified indications or specified circumstances, all limitations on coverage of the items or services because they do not meet those specified indications or circumstances are based on § 1862(a)(1) of the Act. Where coverage of an item or service is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item or service is not mentioned at all in the CMS Manual System the Medicare contractor is to make the coverage decision, in consultation with its medical staff, and with CMS when appropriate, based on the law, regulations, rulings and general program instructions.

- Medicare National Coverage Determination Manual, CMS Pub. 100-03, Chapter 1, Foreword, Paragraph A

# LCDs

- Issued by contractor.
- Apply to limited contractor's geographic territory.
- Subject to notice-and-comment (Program Integrity Manual 13.2.4.2).

# LCDs

- NOT binding in the administrative appeals:
  - 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II) (QICs).
  - 42 C.F.R. § 405.1062 (ALJs).
- But see United States ex rel. Ryan v. Lederman, 2014 WL 1910096 at \*5-6 (EDNY May 13, 2014) (claims in violation of LCD are false because “guidance can be mandatory”).

# Medicaid Manuals

- Many states issue Medicaid manuals.
- Allina doesn't directly apply to these state materials.

# Medicaid Manuals

- Principles of administrative law vary from state to state:
  - Minnesota—unpromulgated rule doctrine.
  - Wisconsin—Supreme Court and statute discontinuing deference to agency interpretations.

# Take Aways

- Be skeptical of the Manuals!
- Refunding based on the Manuals is almost always ill-advised.
- Trace the requirement up the hierarchy of authority.
- The details matter.

# Questions?

# Contact Information



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