November 1, 2013
Fraud and Abuse Update: *Tricks and Treats*

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Major Anti-Fraud Statutes & Regulations

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Major Anti-Fraud Statutes & Regulations

- Federal False Claims Act
- Maine False Claims Act
- Federal Anti-Kickback Statute
- Federal Physician Self-Referral Law (“Stark Law”)
- Maine Health Care Practitioner Self-referral Act

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FEDERAL FALSE CLAIMS ACT
31 U.S.C. **§§ 3729–3733**

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Federal False Claims Act

- Liability for any person who "knowingly" presents or causes to be presented false or fraudulent claims to the US government for payment
  - No requirement that the person submitting the claim has actual knowledge that the claim is false.
  - A person who acts in reckless disregard or in deliberate ignorance of the truth or falsity of the information, also can be found liable.

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Federal False Claims Act

- "Qui Tam" provisions allow private citizens (relators) to bring suits under the FCA on behalf of the government (and obtain share of settlement or judgment).
- Penalties include treble damages and fines of up $11,000 per claim filed.

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Federal False Claims Act

- Examples of violations:
  - Billing for services not rendered or products not delivered
  - Misrepresenting services rendered or product provided
    - e.g., upcoding, inappropriate coding

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Federal False Claims Act

- Examples of violations:
  - Billing for services that are not "medically necessary"
    - e.g., furnishing services in excess of the patient's needs, based on their diagnosis; or furnishing a battery of diagnostic tests, where, based on the diagnosis, only a few were needed
  - "Unbundling" services or products
  - Kickbacks or Stark violations

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What are the Current Targets of FCA Investigations

- Physical Therapy in Long Term Care facilities
- Hospice
- Off-label marketing

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What You Need to Keep an Eye on to Avoid Allegations of FCA Violations

- Billing
  - Appropriate payor sources are billed
  - Services are actually rendered
  - Coding is appropriate
- Documentation
  - Includes all necessary signatures
  - Complete
  - Supports diagnosis & treatment
- Compliance Audits
- Incentive programs

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MAINE FALSE CLAIMS ACT
22 M.R.S. § 15

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Maine False Claims Act

- Largely mirrors the Federal False Claims Act pre-2009
  - Before amendments to Federal FCA in FERA, Dodd-Frank, and Affordable Care Act

- BUT, no *qui tam* provisions (There have been recent Legislative proposals to broaden the Maine law, and there is at least one title pending introduction in the upcoming session.)

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Maine False Claims Act (continued)

- March 2013 OIG Guidelines for Evaluating State False Claims Acts
  - Suggests that Maine FCA may not be in compliance for Maine to receive Medicaid incentives

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Anti-Kickback Statute
42 U.S.C. § 1320a-7b(b)

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Anti-Kickback Statute

- Criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs
  - (*e.g.*, drugs, supplies, or health care services for Medicare or Medicaid patients)

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Anti-Kickback Statute

- Remuneration includes anything of value
  - E.g. cash, tickets, free rent, vacations, excessive compensation for medical directorships or consultancies.
- Liability applies to both the recipient and the giver of the kickback
- Penalties include fines, jail terms, exclusion from participation in the Federal health care programs.

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Anti-Kickback Statute

- Examples of potential violations:
  - Physician requesting or accepting payment from manufacturers for a meal, reception or entertainment event
  - Physicians receiving payment from, or expenses paid by, a device manufacturer to attend a professional association's annual conference without providing any service to the manufacturer.

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What You Need to Keep an Eye on to Avoid Allegations of Kickbacks

- *Keep an eye on the OIG's published Fraud Alerts and Advisory Opinions addressing kickback issues; these provide a good sense of what is considered actually damaging to the federal health care financing system and what is benign*
- *Review the statutory and regulatory safe harbors. Even if a proposed arrangement does not fit squarely, these may suggest opportunities to seek a favorable advisory ruling*

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Physician Self-Referral Law ("Stark Law") 42 U.S.C. § 1395nn

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Stark Law

- Prohibits physicians from referring patients to receive “designated health services” payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies.

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Stark Law

- Strict liability statute – no proof of specific intent to violate the law is required.
- Penalties include fines as well as exclusion from participation in the Federal health care programs.

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Stark Law

- Examples of potential violations:
  - Compensation to physician groups above Fair Market Value
  - Compensation to physician groups based on volume of referrals
  - Discounted rental arrangements that do not reflect Fair Market Value

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Recent Developments With Stark Law

- *Halifax*
  - extending Stark liability to Medicaid?
- *Tenet*
  - *Leasing space to referring physicians at favorable terms may be basis for violation*
- *Tuomey*
  - *Good faith belief that arrangement complies with Stark exception does not prevent liability*
  - *Limitations on advice of counsel defense*

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State Self-Referral: 22 M.R.S. § 2085

Provider investor may refer a patient

- only when provider
- **directly provides** health services
- **within the facility** and will be
- **personally involved** with the provision of care to the referred patient.

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Exemptions & Exceptions

- There are numerous exemptions and exceptions listed in the statute.

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Recent Enforcement Actions

Thanks to Dennis P.H. Mihale, MD, MBA, President & Chief Medical Officer, Chelsea Management Group for the next three slides

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2012 Fraud Statistics

- $3.0 billion in health care fraud judgments and settlements
- 1,131 new criminal health care fraud investigations involving 2,148 potential defendants
- 2,032 health care fraud criminal investigations pending, involving 3,410 potential defendants
- 826 defendants were convicted of health care
- DOJ opened 885 new civil health care fraud investigations and had 1,023 civil health care fraud matters pending
- HHS/OIG excluded 3,131 individuals and entities

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Uptick in Physician Prosecution

This slide courtesy of Dennis P.H. Mihale, MD, MBA, President & Chief Medical Officer, Chelsea Management Group

September 30, 2013; U.S. Attorney; Southern District of Florida Miami Physician Indicted in Medicare Fraud Scheme

September 27, 2013; U.S. Attorney; Eastern District of Tennessee Cleveland Doctor Indicted For Fraud and Money Laundering

September 24, 2013; U.S. Attorney; Eastern District of Pennsylvania Doctor Sentenced for Running Pill Mill and Contributing to a Death

September 18, 2013; U.S. Attorney; Eastern District of Michigan Oncologist Charged in Superseding Indictment with Medically Unnecessary Cancer Treatments
Scheme

September 16, 2013; U.S. Department of Justice "No Show" Doctor Sentenced to 151 Months in Prison in Connection with $77 Million Medicare Fraud Scheme

September 13, 2013; U.S. Department of Justice Florida Doctors, Hospitals and Clinics to Pay $3.5 Million to Settle Allegations of Improper Medicare, Medicaid and TRICARE Billing

September 11, 2013; U.S. Attorney; District of New Jersey Two Doctors and a Salesman Admit Roles in Bribes-For-Test Referrals Scheme Involving New Jersey Clinical Laboratory

September 10, 2013; U.S. Department of Justice Medical Supply Company Officer and Southern California Physician Sentenced for $1.5 Million Medicare Fraud

August 27, 2013; U.S. Department of Justice MRI Diagnostic Testing Company, Imagimed LLC, and Its Former Owners and Chief Radiologist to Pay $3.57 Million to Resolve False Claims Act AllegationsClick here to review our disclaimers

August 27, 2013; U.S. Attorney; Northern District of Illinois Mobile Doctors' Chicago CEO and Doctor Arrested on Federal Health Care Fraud Charges; Offices Searched in Three Cities

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FCA Prosecution: Just as Painful?

- **7/30/2013** Malik, Dr. Istiaq D.D.C. $17,000,000.00 Health Care Double billing for nuclear stress tests
- **7/18/2013** Park Avenue Medical Associates S.D.N.Y. $1,000,000.00 Health Care Ineffective psychotherapy services
- **7/3/2013** Sound Inpatient Physicians Inc. W.D. Wash. $14,500,000.00 Health Care Inflated claims for hospitalists
- **7/2/2013** East Tennessee Hematology-Oncology E.D. Tenn. $4,250,000.00 Health Care Misbranded unapproved chemotherapy drugs
- **6/20/2013** Chan, Dr. Alfred W.D. Wash. $3,100,000.00 Health Care Overbilling for cancer treatment drugs
- **5/29/2013** Dermatology & Skin Cancer Prevention Center N.D. Ga. $600,000.00 Health Care Claims submitted for services by other doctor
- **2/11/2013** Wasserman, Steven J., M.D. M.D. Fla. $26,100,000.00 Health Care Accepting kickbacks; unnecessary services

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Dr. File Press Release: Closer to home

Freeport Doctor Settles Federal Health Care Billing Complaint – 10/1/12
U.S. Attorney "Thomas E. Delahanty II today announced that **Peter M. File**, D.O., an osteopathic physician with offices in Freeport, Maine and Alexandria, Virginia, has agreed to pay $321,443 to settle claims involving false billings to the Medicare and TRICARE federal health care programs."
"The United States filed a civil complaint on September 28, 2012 alleging that **Dr. File** violated the federal False Claims Act between October 2004 and June 2011 by billing Medicare and TRICARE for providing osteopathic manipulative treatment, evaluation and management services to patients in violation of applicable Medicare billing guidelines. The complaint alleged that **Dr. File** submitted $315,943 in false claims to Medicare and TRICARE. The complaint sought damages equaling the full amount of the false claims, along with $5,500 in statutory penalties, for a total of $321,443. **Dr. File** cooperated in the investigation."

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Credible Allegations of Fraud

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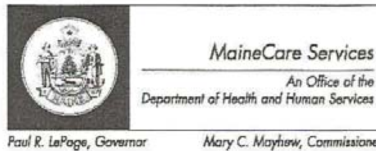
Letter your clients may receive before you are aware there is a problem



Department of Health and Human Services
MaineCare Services
Member Services
11 State House Station
Augusta, Maine 04333-0011
Toll Free (800) 977-6740
TTY Users: Dial 711 (Maine Relay)

September 23, 2013

Dear MaineCare Member:

I am sending you this letter because our records show that you are getting services from . I want you to know that you might see a disruption in the services you get.

If your services are disrupted, please call Member Services at **1-800-977-6740.** If you are deaf or hard of hearing and have a TTY machine, the TTY number is **711**. Member Services has names and telephone numbers of other Behavioral Health and Mental Health service providers in your area who are taking new patients.

If you got this letter and are not getting services from this agency right now, please contact Greg Nadeau from the Department of Health and Human Services at **207-287-9280.**

Sincerely,

Stefanie Nadeau -> 287-2093

Stefanie Nadeau, Director
Office of MaineCare Services

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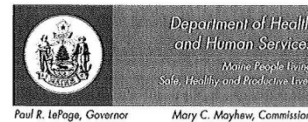
The letter you may receive



Department of Health and Human Services
Financial Services - Audit
11 State House Station
Augusta, Maine 04333-0011
Tel: (207) 287-2403; TTY users call Maine Relay 711
Fax: (207) 287-2601
Fraud Hotline: (866) 348-1129

Subject: Suspension of Medicaid Payments

Dear Provider:

Pursuant to federal rule 42 CFR § 455.23(a), Maine statute 22 M.R.S. §1714-E, and 10-144 Department of Health and Human Services MaineCare Benefits Manual (MBM) Chapter I, section 1.20-3, the Division of Audit, Program Integrity (PI), **must** suspend all MaineCare payments to a provider upon a determination that there exists a credible allegation of fraud for which an investigation is pending. PI has suspended payments to on this basis.

The source of the allegation may be:

1. A reliable fraud hotline complaint;
2. Claims data mining;
3. Patterns identified through a provider audit;
4. Patterns identified through a civil false claims case;
5. Patterns identified through a law enforcement investigation; or
6. Another source with one or more indicia of reliability.

PI is not required to disclose any specific information concerning an ongoing investigation. PI has reviewed allegations, facts and evidence carefully prior to taking this action.

The general allegations are: Billing for inappropriate services

As a result of the above-described fraud allegation(s), payments to your agency have been suspended effective September 25, 2013 in accordance with 42 CFR § 455.23 and MBM Chapter I, section 1.20-3. This suspension applies to all services MaineCare claims submitted by the provider number: NPI 1457691263. Any attempt to circumvent this payment suspension action by submitting claims for services performed under this number through other agencies or by utilizing other billing numbers shall result in termination. This letter serves as formal notice of this action.
The payment suspension is for a temporary period. Pursuant to 42 CFR § 455.23(c) and MBM Chapter I, section 1.20-3(D), payment suspension will not continue after either of the following:

1. The agency or the prosecuting authorities determine that there is insufficient evidence of fraud by the provider; or

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Medicaid Suspension based on “Credible Allegation of Fraud:” Overview

- What is a credible allegation of fraud?
  - Federal Perspective
  - State Perspective
- What are the practical consequences for your medical practice?
- Is there anything you can do to prevent it from happening to you?

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Authority: Federal Statutes (ACA §6402(h))

- "The Secretary may suspend payments to a provider . . . pending an investigation of a credible allegation of fraud against the provider . . . unless the Secretary determines there is good cause not to suspend such payments."

42 U.S.C. § 1395y(o).

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Authority: Federal Statutes

- Payment shall not be made for an item or service made “by any individual or entity to whom the State has failed to suspend payments . . . when there is pending an investigation of a credible allegation of fraud against the individual or entity . . . unless the State determines in accordance with such regulations there is good cause not to suspend such payments . . . .”

42 U.S.C. § 1396b(i)(2)(C)

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Authority: Federal Regulations

- The State Medicaid agency must suspend all Medicaid payments to a provider after the agency determines there is a credible allegation of fraud for which an investigation is pending . . . unless the agency has good cause to not suspend payments or to suspend payment only in part.

42 C.F.R. § 455.23(1)

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Authority: Maine Statutes

- The department shall suspend payment in whole or in part to a MaineCare provider when a suspension is necessary to comply with . . . [Federal statutes and regulations].

22 M.R.S. § 1714-E

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Credible Allegation of Fraud: Definition

- may be an allegation, verified by the State, from any source, including:
  - Hotline complaints, Claims data mining, Patterns identified through audits, civil false claims cases, and law enforcement investigations.
- Allegations are credible when they have indicia of reliability and the State has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis.

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Credible Allegation of Fraud: Definition

- "indicia of reliability"
- judiciously
- case-by-case basis
- Fact-based

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Good Cause Exceptions to Suspension

- Law enforcement requests
- Other available remedies
- Written evidence from provider
- Jeopardizes access to care
- Matter ceases to be under investigation
- Not in best interests of Medicaid
- Specific type of claim – only part suspension appropriate

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60 Day Reporting and Returning of Overpayments

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What is required?

42 U.S.C. §1320a-7k(d)

- Report & return within 60 days of "identification"
- Retention– FCA

Proposed Rules: 77 Fed. Reg. 9179 (February 16, 2012).

- "Reasonable Inquiry"
- "With all deliberate speed"
- 10 Year look-back
- Potential CMP liability & Exclusion

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Examples of Overpayments

- Payments for noncovered services
- Payments in excess of the allowable amount for a covered service
- Duplicate payments
- Receipt of Medicare payment when another payor had primary responsibility for payment

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“Identification” means . . .

Identification means that the Provider . . .

- Has actual Knowledge;
- Acts in reckless disregard; or
- Acts in deliberate ignorance . . .

of the existence of the overpayment.

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Existing Self-Disclosure Protocols

- Self-Referral Disclosure Protocol (SRDP)
  - Obligation to return suspended;
  - Obligation to report still exists

- OIG Self Disclosure Protocol (SDP)
  - Obligation to return suspended;
  - Obligation to report satisfied

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Extended Repayment Schedule (ERS)

- "significant documentation"
- "true financial hardship"
- 10 % or greater than the total Medicare Payments

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Elements of report

- Provider's name
- Tax ID
- How error was discovered
- Reason for overpayment
- Health insurance claim number
- Date(s) of service
- Medicare claim control number
- Medicare NPI
- Description of the corrective action plan
- Any corporate integrity agreement with the OIG; or under SDP
- Timeframe and total amount of refund
- Description of any statistical sampling and extrapolation used
- Refund in the amount of the overpayment (unless ERS)

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Reporting Process

- Process the Medicare Contractor uses
- Except for SDPs & SRDPs

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State Reporting and Hardship

- Changes traditional cost reporting protocol
- Office of Audit has indicated receptiveness to hardship requests for installment plans
- Program Integrity, while within Audit, may tend to send installment request directly to DHHS Finance
- Recoupment commences if installment payment missed/late

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Estimated Annual Burden/Cost

TABLE 1—ANNUAL BURDEN REQUIREMENTS AND COSTS ASSOCIATED WITH REPORTING AND RETURNING OF OVERPAYMENTS (§ 401.305)

Number of impacted providers and suppliers	Number of overpayments processed per provider and supplier	Burden per overpayment reported and returned (hours)	Total annual burden (hours)	Hourly labor cost of reporting	Total cost (in millions)
125,000	3–5	2.5	937,500–1,562,500	$37.10	$34.78–$57.97

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Recovery Audit Contractors (RACs)

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What are Recovery Audit Contractors?

- Identify overpayments and underpayments
- Contingency fee - percentage of recoveries.
- Post-payment review
- Limited to 3 year look-back
- Employ clinical staff, coders & Contractor Medical Director (CMD)

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Recovery Audit Review Process

- Automated
- Semi-Automated
- Complex

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Most Frequent RAC findings

- Services d/n meet Medicare's Coverage and Medical Necessity criteria
- Incorrect coding
- Supporting documentation d/n support the ordered service

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How RACs differ from MACs, FIs

- Discussion with Providers
- CMS prior approval
- Issues posted to RA website

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“Issues Under Review” : Example

Issue Number	Issue Name	Type of Review	Provider Type	State(s) Impacted	Date Posted
A000452013	Postpayment Review - Manual Medical Review of Outpatient Therapy Claims Above the $3,700 Threshold	Complex	Skilled Nursing Facility (Part B Only)	CT, DC, DE, MA, MD, ME, NH, NJ, RI, VT	4/22/2013
A000602012	SNF Psychiatric Condition	Complex	Skilled Nursing Facility	CT, DC, DE, MD, ME, MA, NH, NJ, NY, PA, RI, VT	1/18/2013
A000302013	Postpayment Review - Manual Medical Review of Outpatient Therapy Claims Above the $3,700 Threshold	Complex	Private Practice	CT, DC, DE, MA, MD, ME, NH, NJ, RI, VT	4/22/2013

https://www.performantrac.com/IssuesUnderReview.aspx

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RACs: Provider Options

- If agree with determination:
  - Send a check
  - Recoup from future payments
  - Request extended payment plan
  - Appeal
- If not, appeal

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RAC Appeals Process

- Determination
- Redetermination
- Reconsideration
- Office of Medicare Hearing and Appeals
- Medicare Appeals Council
- Federal District Court

For more details see: MLN ICN006562

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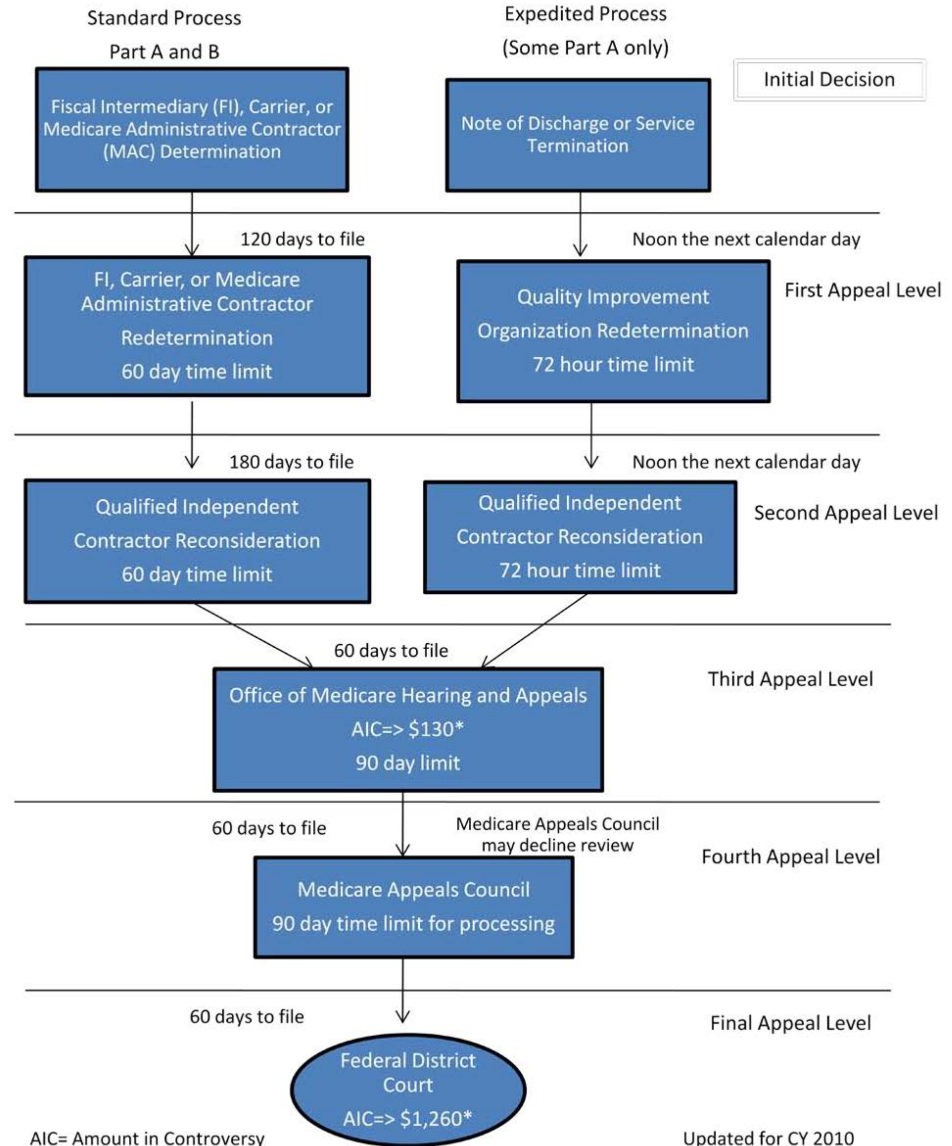
RAC Appeals Process Flowchart



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Collection and Repayment

- MACs handle collections
- May involve offsets
- Recoupment 41 days after date of demand letter / Adjustment

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What can you do to limit your exposure?

- Check RAC websites
  - www.cms.hhs.gov/rac
- Check OIG and CERT reports
  - www.oig.hhs.gov/reports.html
  - www.cms.hhs.gov/cert
- Audit yourself for compliance and learn from mistakes

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MaineCare Appeals

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MaineCare Appeals Procedures

- 60 days to file Request for Informal Review
- Applies to final decisions of auditors, PI Notices of Violation, and other MaineCare agency actions
- Informality suffices to start the process – but substantial risk of waiving issues not raised
- 30-day supplementation opportunity – not clear in rules

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MaineCare Appeals Procedures (cont'd)

- If appeal rights not given, questions arise about whether the action is subject to review at that point
- Example – RAC demands with no DHHS Notice of Debt. Solution: "bulk" notices of debt followed by Request for Informal Review

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MaineCare Appeals Procedures (cont'd)

- Officially Informal Review is "Desk only"
- Opportunities to Meet
- Variable timing of decision-making
- Final Informal Review Decision

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Final MaineCare Administrative Level

- 60 days to file Administrative Appeal
- No issues not raised in Informal Review – but opportunity to finesse
- Hearings Unit – DHHS employed Hearing Officers acting on behalf of Commissioner through Order of Reference
- Role of Audit's "Fair Hearing Report"

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What Do You Do When The Feds Come Looking for You?

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How Should You Respond to a Search Warrant?

- Call your lawyer!!
  - Investigators will generally wait to commence their search until your counsel arrives if you ask

- Request the name of the prosecutor conducting the investigation, a copy of the search warrant, and application to the court

- Once the search begins, do not interfere with the investigators or prevent them accessing anything listed in the search warrant.
  - But note your objection to an expansion of the search beyond the areas specified in the warrant

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How Should You Respond to a Search Warrant?

- Keep an index of documents seized and/or copied
- Designate an employee to take notes on the following:
  - the precise areas and files searched;
  - the manner in which the search was conducted;
  - employees who were questioned or whose interview was requested;
  - all verbal communications with investigators
- At the conclusion of the search, request an inventory of documents seized.

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How Should You Respond to a CID or Subpoena?

- Call your lawyer!!
  - Or discuss with in-house counsel whether to retain outside counsel

- Ensure document preservation measures are put in place
  - Immediately suspend normal document destruction including ESI
  - Ensure appropriate personnel are put on notice of their document preservation obligations

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How Should You Respond to a CID or Subpoena?

- Have counsel contact the lead government investigator to ascertain whether the scope, timing, and method of production is negotiable
  - 30 days is likely an insufficient amount of time to identify and gather all of the information requested
  - Sometimes counsel can convince the government that identifying and gathering certain types of information requested would be unduly burdensome (at least at the initial phase)

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How Should You Respond to a CID or Subpoena?

- Determine whether you want object to any of the requests contained in the subpoena
  - Recognizing that it will be difficult to quash or modify a government subpoena

- Identify, gather, and review the information responsive to the government's requests

- Be prepared for additional requests for information from the government

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Questions?

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