William M. Bankston, Shareholder Christopher M. Brecht, Associate Julia M.I. Holden Davis, Shareholder\* Chris D. Gronning, Shareholder Barbra Z. Nault, Shareholder Steven T. O'Hara, Shareholder Also Admitted in Weshington

## Patient Protection and Affordable Care Act The 60-Day Clock is Ticking – Now What?

### I. What is the 60-Day Rule?

- On February 16, 2012, the Department of Health and Human Services, Centers for Medicare & Medicaid Services proposed a rule (available at 77 FR 9179) that would require providers and suppliers receiving funds under the Medicare program to report and return overpayments on the later of:
  - a) **60 days** after the date on which the overpayment was **identified**; or
  - b) the date on which a corresponding cost report is due
- Note: As of present, proposed rule only applies to Medicare Part A and B providers and suppliers. Other stakeholders, including MAOs, PDPs, and Medicaid MCOs "will be addressed at a later date."
- Also Note: The proposed rule reminds all stakeholders that even without a final regulation all are subject to the statutory requirements and could face potential liability under the False Claims Act, the Civil Monetary Penalties Law, and exclusion from federal healthcare programs (discussed in Section IV below)
- This proposed rule is meant to implement Section 6402(a) of the Affordable Care Act ("ACA") which created a new section 1128J(d) of the Social Security Act ("SSA") which requires:
  - a) a person who has received an overpayment to **report and return** the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate; and

William M. Bunkston, Shareholder Christopher M. Brecht, Associate Julia M.I. Holden Davis, Shareholder Chris D. Gronning, Shareholder Barbra Z. Nault, Shareholder Steven T. O'Hara, Shareholder 'Also Admitted in Washington

- b) to **notify** the same party to whom the overpayment was returned of the reason for the overpayment
- The Statute Language Implemented (1128J(d)):

Reporting and Returning of Overpayments.—

- (1) In general.—If a person has received an overpayment, the person shall—
  - (A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
  - (B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
- (2) Deadline for reporting and returning overpayments.—An overpayment must be reported and returned under paragraph (1) by the later of—
  - (A) the date which is 60 days after the date on which the overpayment was identified; or
  - (B) the date any corresponding cost report is due, if applicable.
- (3) Enforcement.—Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title [123].
- (4) Definitions.—In this subsection:
  - (A) Knowing and knowingly.—The terms "knowing" and "knowingly" have the meaning given those terms in section 3729(b) of title 31, United States Code.
  - (B) Overpayment.—The term "overpayment" means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.
  - (C) Person.—

William M. Bankston, Shareholder Christopher M. Brecht, Associate Julia M.I. Holden Davis, Shareholder Chris D. Gronning, Shareholder Barbra Z. Nault, Shareholder Steven T. O'Hara, Shareholder Also Admitted in Washington

- (i) In general.—The term "person" means a provider of services, supplier, medicaid managed care organization (as defined in section  $\underline{1903(m)(1)(A)}$ ), Medicare Advantage organization (as defined in section  $\underline{1859(a)(1)}$ ), or PDP sponsor (as defined in section  $\underline{1860D-41(a)(13)}$ ).
- (ii) Exclusion.—Such term does not include a beneficiary.

# II. Some Background – What is an overpayment? What are the policy goals driving this proposed rule?

- Overpayment The SSA defines an overpayment as: any funds that a person receives or retains under the SSA to which the person, after applicable reconciliation, is not entitled under the SSA. The proposed rule would adopt this definition. Examples:
  - a) Medicare payments for noncovered services;
  - b) Medicare payments in excess of the allowable amount for an identified covered service;
  - c) Errors and nonreimbursable expenditures in cost reports;
  - d) Duplicate payments;
  - e) Receipt of Medicare payment when another payor had the primary responsibility for payment;
  - f) Incorrectly coded services resulting in increased reimbursement;
  - g) Death of a patient prior to a service date on a claim submitted for payment;
  - h) Violations of the Stark Act (see Section III below); and
  - i) Overpayments that arise due to violation of anti-kickback statute (e.g., device manufacturer pays physician to induce physician to implant its devices, but note, provider or supplier must be a party to the kickback arrangement or will not have "identified" the overpayment)



- Note: Estimated payments and interim payments are made by Medicare with knowledge that a reconciliation will be completed with actual costs; therefore, overpayment does not exist until after reconciliation.
- Note: Providers must accurately report overpayments at the time they submit any cost reports to Medicare, whether an initial or amended submission.
- Policy Goals: Compliance with statutory requirements; promote the furnishing of high quality care; and protect the Medicare Trust Funds against fraud and improper payments. From the proposed rule: "As Medicare spending has grown, we have increased our efforts to reduce fraud, waste, and abuse in the Medicare program."
- **Note:** The agency has "twice proposed but did not finalize rules that would have amended our regulations related to Medicare overpayments."
  - a) These attempts came in 1998 and 2002
  - b) **1998 Attempt**: harmonize Social Security Administration regulations with Health Care Financing Administration regulations by:
    - -explicit criteria and the circumstances by which a provider or supplier can be relieved of liability for an overpayment on basis of being "without fault" -grant Peer Review Organizations the authority to make without-fault determinations
    - -attempt to reduce amount of liabilities passed on to individuals thereby increasing amount of money recovered

William M. Bankston, Shareholder Christopher M. Brecht, Associate Julia M.I. Holden Davis, Shareholder\* Chris D. Gronning, Shareholder Barbra Z. Nault, Shareholder Steven T. O'Hara, Shareholder \*\*Also Aurritted in Washington

- -SSA regulations do not take into account the significant difference between the role of the individual in receiving cash benefits versus receiving Medicare benefits -fault turned on "exercising reasonable care"
- c) **2002 Attempt**: supplement and modify the 1998 Attempt -add other entities subject to returning overpayment (in addition to providers, suppliers, and individuals) to include MCOs that provide Medicare services to Medicare beneficiaries

#### III. What are the Important Highlights in the Proposed Rule?

- The proposed rule is effective now because the statutory requirements must be met whether or not final rule is ever adopted, or subsequent rules are ever adopted to provide instructions to MAOs, PDPs, and Medicaid MCOs.
  - -Note: beneficiaries are **not** "persons" within the meaning of Section 1128J(d) nor does the proposed rule attempt to include beneficiaries
- Overpayment must be reported and returned within 60 days and time runs from date person identifies the overpayment.
  - -Identifies means having actual knowledge of the information, acting with deliberate ignorance of the truth or falsity of the information, or acting with a reckless disregard of the truth or falsity of the information. No need for proof of specific intent to defraud. These definitions in 1128J(d) are defined as in the False Claims Act.
  - -By defining **identifies** in this way the proposed rule creates a **duty to inquire**. The proposed rule calls this an "obligation to



make reasonable inquiry," but probably better thought of as a duty.

• What is a "reasonable inquiry?" Not defined, but proposed rule states that the inquiry should be made with "all deliberate speed after obtaining [] information." Additionally, if "there is reason to suspect an overpayment, but a provider or supplier fails to make a reasonable inquiry into whether an overpayment exists, it may have been found to have acted in reckless disregard or deliberate ignorance of any overpayment."

-Note: Proposed rule also gives example of an overpayment being found in a government audit. This triggers the duty to inquire (reasonably) and report and return the overpayment.

• Self-disclosure through the Stark Medicare Self-Referral Disclosure Protocol suspends the 60-day deadline to return overpayments but still must report the overpayment.

For details see:

https://www.cms.gov/PhysiciansSelfReferral/Downloads/6409\_SRDP \_Protocol.pdf

If provider or supplier uses the Office of Inspector General Self-Disclosure Protocol then obligation to return is suspended until settlement or the provider or supplier withdraws or is removed. The notification of OIG will satisfy the reporting requirement, but still must be done in 60 days.

For details see: https://oig.hhs.gov/authorities/docs/selfdisclosure.pdf

The proposed rule implements its requirements using the existing voluntary refund process renamed the Self-Reported Overpayment Refund Process. Providers and suppliers use forms that each Medicare Contractor (fiscal intermediary, carrier, or Medicare administrative contractor) provides online. This will require a summary of why the refund is being made including: how the error



William M. Bankston, Shareholder Christopher M. Brecht, Associate Julia M.I. Holden Davis, Shareholder Chris D. Gronning, Shareholder Barbra Z. Nault, Shareholder Steven T. O'Hara, Shareholder 'Also Admitted in Washington

was made; a description of the corrective action plan to ensure error is not repeated; the reason for the refund; whether the provider or supplier has a corporate integrity agreement with the OIG or is under OIG Self-Disclosure Protocol; and other information.

-Note: The agency recognizes that not all forms are uniform at present but plans to develop uniformity.

• There is a **10 year lookback period**. This means overpayments must be reported and returned only if a person identifies the overpayment within 10 years of the date the overpayment was received. 10 years was chosen as it is consistent with the outer limits of the False Claims Act. The proposed rule also seeks the ability to re-open overpayments reported for a period of 10 years.

#### IV. What Liabilities May Arise for Noncompliance?

- First, there are **no safe harbors** in the proposed rule. The process of returning and reporting overpayments cannot resolve any potential False Claims Act or OIG administrative liability. **But**, the returning of the overpayment may limit any False Claims Act or administrative liability resulting from the retention of the overpayment.
- Under the proposed rule Medicare Contractors will scrutinize overpayments received through the prescribed process and may make referrals to OIG whenever the Medicare Contractors believe circumstances warrant such a referral.
- In sum, noncompliance will expose a supplier or provider to liability under the False Claims Act, the Civil Monetary Penalties Law (when a person knows of an overpayment and does not report and return), and possible exclusion from the federal program.

#### V. What Issues Have Been Raised in Public Comment?



- The American Association of Bioanalysts and the National Independent Laboratory Association
  - -Approve of the uniform reporting form
  - -Does not believe 60 days will be long enough to formulate amount of overpayment
  - -Would like more clarification on when duty to inquire arises
  - -Believes unique position of laboratories should be considered as they are not in a position to determine if tests are medically necessary
  - -Believes 10 year lookback is unreasonably burdensome
- The American Medical Association, AMDA, American Academy of Allergy, Asthma, and Immunology, *et al.* 
  - -Believes the duty to inquire imposed by the definition of "identify" creates a perpetual duty on physicians that is "extremely burdensome."
  - -The start of the 60-day period should be better defined
  - -"Adamantly" opposed to the 10 year lookback period
  - -Due Process should be provided for an administrative appeal process to appeal an overpayment determination
  - -Reporting requirements should be omitted
  - -Uniform reporting form should be published in tandem with final rule