Rockwell Intl Corp.s Impact on Qui Tam Actions under the False Claims Act

2008 Emerging Issues 1726

Rockwell Intl Corp.s Impact on Qui Tam Actions under the False Claims Act

By Robert W. Lundy Jr.

December 31, 2007

SUMMARY: Hooper, Lundy & Bookman on Rockwell Int'l Corp. v. United States. The federal False Claims Act (FCA), *31 U.S.C. §§ 3729* 3733, continues to be a major weapon used, and at times abused, by the government and qui tam relators, private whistle-blowers, in cases of suspected health care fraud and abuse. This commentary discusses the impact of the Rockwell Int'l case on qui tam actions under the federal False Claims Act.

PDF LINK: Click Here for Enhanced PDF of Commentary

ARTICLE: The federal False Claims Act (FCA), *31 U.S.C. §§ 3729* 3733, continues to be a major weapon used, and at times abused, by the government and qui tam relators, private whistle-blowers, in cases of suspected health care fraud and abuse. Through recent Deficit Reduction Act amendments, Congress is encouraging states to adopt or amend state laws to model the federal FCA, including its whistle-blower provisions, to fight Medicaid fraud and abuse. Consequently, health care providers and others involved in the health care industry can expect even more investigations and litigation.

The FCA is so widely used by private whistle-blowers because, if they prevail in litigation on behalf of the government, they may share in the proceeds of the lawsuit or settlement and they are awarded attorneys fees. Such private parties initiate the majority of FCA cases. However, there are limits to qui tam actions. For example, under the FCA, the federal courts lack jurisdiction over qui tam actions that are based upon publicly disclosed allegations or transactions unless the action is brought by the federal government, itself, or the qui tam relator is the original source of the information. The interpretation of public disclosure, original source and related terms in the FCA has been the subject of considerable litigation.

On March 27, 2007, the United States Supreme Court decided in *Rockwell International Corp. v. The United States, 549 U.S. 1397, 167 L. Ed. 2d 190 (2007)*, that in order for a federal court to have jurisdiction over an FCA qui tam action, the qui tam relator must be the original source of the ultimate allegations advanced against the defendant(s), if those allegations have been the subject of a prior public disclosure. Thus, as is often the case, if the original allegations in a qui tam action are subsequently changed or added to, the qui tam relator must be the original source of the revised allegations. In *Rockwell*, this was not the case, and, therefore, the Court concluded the qui tam relator in that case could not share in the $4.2 million recovery obtained after the government intervened in the action.

The Supreme Courts decision makes it more difficult for professional qui tam relators and other persons relying on publicly disclosed information to maintain FCA actions. The Courts decision may also impliedly reflect continuing judicial skepticism about qui tam cases in general.

ABOUT THE AUTHOR(S):

Robert W. Lundy, Jr. graduated with high honors from Yale University in 1972. In 1975, he received his J.D from the University of California at Los Angeles, where he was the recipient of the Distinguished Advocate Award.

Since 1978, Mr. Lundy has specialized in health care business transactions, including joint ventures, private placements, structuring of physician organizations, financing, acquisitions, mergers, alternative delivery systems, and licensing and certification matters. In 1987, together with Patric Hooper and Lloyd Bookman, formed the national health care law firm of Hooper, Lundy & Bookman in Los Angeles. As a founding member of Hooper, Lundy & Bookman, Inc., Mr. Lundy has continued to represent health care providers in a wide variety of business transactions.

Mr. Lundy was named one of Southern Californias Super Lawyers by L.A. Magazine for 2004, 2005, 2006 and 2007, was recognized in 2005, 2006, and 2007 by Chambers USA as one of the top health care lawyers in California and was nationally recognized as one of the Outstanding Healthcare Transaction Lawyers of 2003 by Nightingales Healthcare News. Mr. Lundy is the General Editor of LexisNexis/Matthew Benders five volume publication entitled Treatise on Health Care Law.

Hooper, Lundy & Bookman is the largest full service law practice in the country dedicated solely to the representation of health care providers. With offices in Los Angeles, San Francisco and San Diego, and clients in 46 states, Hooper Lundy & Bookman meets the business, litigation and regulatory needs of a broad array of health care providers--ranging from the largest national health care organizations to community hospitals and individual physician practices.

CMS Proposes Changes to Clinical Trial Policy

2008 Emerging Issues 1712

CMS Proposes Changes to Clinical Trial Policy

By Robert W. Lundy Jr.

December 28, 2007

SUMMARY: Hooper, Lundy & Bookman on Proposed Changes to CMS Clinical Trial Policy. On April 10, 2007, the Centers for Medicare and Medicaid Services (CMS) issued a Proposed Decision Memo outlining potential revisions to the Medicare National Clinical Trial Policy, which governs what services rendered as part of clinical research will be covered by Medicare. The memo proposes significant changes to protocols, general and clinical standards, public information and approval processes. This commentary analyzes the proposed changes and the potential impact of the new Clinical Trial Policy.

PDF LINK: Click Here for Enhanced PDF of Commentary

ARTICLE: On April 10, 2007, the Centers for Medicare and Medicaid Services (CMS) issued a Proposed Decision Memo outlining potential revisions to the Medicare National Clinical Trial Policy, which governs what services rendered as part of clinical research will be covered by Medicare. The memo proposes significant changes to protocols, general and clinical standards, public information and approval processes.

Incorporating the changes, CMS proposes to change the name of the National Coverage Determination (NCD) to Clinical Research Policy in response to commentators concerns that the title Clinical Trial Policy has been interpreted to exclude studies other than clinical trials.

The proposed revisions to the NCD contain a definition of clinical research, which was missing previously. Clinical research will be defined as: The observation of events in groups of individuals who share a particular characteristic, such as a symptom or illness; or who have the same treatment or diagnostic test provided for a symptom or illness. Inferences are made based on comparisons of predefined health outcomes among groups. Procedures are in place to assure that the rights, safety, and wellbeing of research study participants are protected. Research studies need to conform to all applicable Federal regulations concerning human subject protection and privacy including 45 C.F.R. Part 46 and Parts 160 and 164. The new definition also contains three examples of types of clinical trials that might be supported by Medicare.

Clinical Trial Standards. Under the proposal, clinical trial standards will be reclassified into three categories: 1) general standards for a scientifically and technically sound clinical research study; 2) Medicare-specific standards of a clinical research study; and 3) National Coverage Determination Coverage with Evidence Development standards. The

general standards will now include the seven highly desirable characteristics of a qualified trial, which will be modified slightly. The proposed NCD also renames these general standards for a scientifically and technically sound clinical research study and adds an additional standard requirement: the research study must now have a written protocol.

Proposed revisions to the other seven general standards are as follows: 1) the principle purpose of the research study is to test whether a particular intervention potentially improves the participants health outcomes; 2) the research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use; 3) the research study does not unjustifiably duplicate existing studies; 4) the research study design is appropriate to answer the research question being asked in the study; 5) the research study is sponsored by an organization or individual capable of executing the proposed study successfully; 6) the research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is FDA-regulated, it also must be in compliance with 21 CFR Parts 50 and 56; 7) all aspects of the research study are conducted according to the appropriate standards of scientific integrity.

With regard to the Medicare-specific standard of therapeutic intent, the NCD proposes to directly address phase I clinical trials and clarify the definition of therapeutic intent as follows: The clinical research study is not designed to exclusively test toxicity or disease pathophysiology. Research studies, including some Phase I trials, whose protocols commit to measuring therapeutic outcomes as one of the objectives, may meet this standard only if the disease being studied is chronic, life threatening, or debilitating.

An additional new Medicare-specific standard is proposed that will require public release of all primary and secondary outcomes measures as the analyses are completed. Public dissemination of study results can be made in peer-reviewed publications or in suitable public web-based databases. The proposed NCD will further require that each research study is registered on the NIH/National Library of Medicine clinical trials registry, clincialtrials.gov, prior to the enrollment of the first study subject.

Protocols and Approval Processes. CMS has also announced its proposed intention that covered study protocols address all populations affected by the technology under investigation in the study. Specifically, CMS proposed to require that subgroup differences (such as those based on gender, race/ethnicity, or age) be defined and that study protocols discuss how the study will evaluate any differences discovered. Additionally, research study protocols will be required to contain a discussion of how the results may impact the Medicare population. These new requirements will be included as Medicare-specific standards.

Several important changes are also proposed for approval processes that assure the general standards are met. For example, CMS proposed to delete the deemed status of Investigational New Drug (IND) Exempt trials and instead require that IND Exempt studies meet the other approval process criteria. The selfcertification process, which was never implemented, will likewise be deleted. Also, a new proposed approval process will be added if a study is required and approved by the FDA as a post-approval study. CMS acknowledged the need to explore alternative processes for approving other types of studies such as studies of orphan drugs, and is open to public comment regarding this.

The proposed NCD also contains new or revised definitions of Medicare-covered items and services, including routine costs, administrative services, and investigational costs or services.

The Proposed Decision Memo is available at http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=186.

ABOUT THE AUTHOR(S):

Hooper, Lundy & Bookman is the largest full service law practice in the country dedicated solely to the representation of health care providers. With offices in Los Angeles, San Francisco and San Diego, and clients in 46 states, Hooper Lundy & Bookman meets the business, litigation and regulatory needs of a broad array of health care

providers--ranging from the largest national health care organizations to community hospitals and individual physician practices.

Robert W. Lundy, Jr. graduated with high honors from Yale University in 1972. In 1975, he received his J.D from the University of California at Los Angeles, where he was the recipient of the Distinguished Advocate Award.

Since 1978, Mr. Lundy has specialized in health care business transactions, including joint ventures, private placements, structuring of physician organizations, financing, acquisitions, mergers, alternative delivery systems, and licensing and certification matters. In 1987, together with Patric Hooper and Lloyd Bookman, formed the national health care law firm of Hooper, Lundy & Bookman in Los Angeles. As a founding member of Hooper, Lundy & Bookman, Inc., Mr. Lundy has continued to represent health care providers in a wide variety of business transactions.

Mr. Lundy was named one of Southern Californias Super Lawyers by L.A. Magazine for 2004, 2005, 2006 and 2007, was recognized in 2005, 2006, and 2007 by Chambers USA as one of the top health care lawyers in California and was nationally recognized as one of the Outstanding Healthcare Transaction Lawyers of 2003 by Nightingales Healthcare News. Mr. Lundy is the General Editor of LexisNexis/Matthew Benders five volume publication entitled Treatise on Health Care Law.

CMS Regulations Affect Changes to Medicare's Anti-Markup Rules

2008 Emerging Issues 1713

CMS Regulations Affect Changes to Medicare's Anti-Markup Rules

By Robert W. Lundy Jr.

December 28, 2007

SUMMARY: Hooper, Lundy & Bookman on new CMS Regulations Affecting Physician Diagnostic Services and IDTF Timeshare Arrangements. CMS issued regulations in late 2007 that will have a significant adverse affect on many physicians and medical groups that bill Medicare for diagnostic services. The regulations will also negatively affect many existing timeshare arrangements, under which independent diagnostic testing facilities (IDTF) share space or equipment with medical practices. This commentary analyzes these regulations and their impact on Physician Diagnostic Services and IDTF Timeshare Arrangements.

PDF LINK: Click Here for Enhanced PDF of Commentary

ARTICLE: The Centers For Medicare and Medicaid Services (CMS) issued regulations in late 2007 that will have a significant adverse affect on many physicians and medical groups that bill Medicare for diagnostic services. The regulations will also negatively affect many existing timeshare arrangements, under which independent diagnostic testing facilities (IDTF) share space or equipment with medical practices. The regulations were published in the Federal Register on November 27, 2007 and will be effective on January 1, 2008. *72 FR 66222;* 42 CFR § 409; 42 CFR § 410; 42 CFR § 411; 42 CFR § 413; 42 CFR § 414; 42 CFR § 415 42 CFR § 418; 42 CFR § 423; 42 CFR § 424; 42 CFR § 482; 42 CFR § 484; and 42 CFR § 485.

The most significant change in the new regulations relates to Medicares so-called anti-markup rules, which prohibit physicians and medical groups from marking up, or making any profit from, the technical or facility component of certain diagnostic tests purchased from outside suppliers. While the application of the anti-markup rule has been somewhat unclear in the past, it generally permitted physicians and medical groups to bill and mark-up diagnostic tests as long as the physician or a member of the group supervised the test.

Under the new 2008 changes, the anti-markup rule has been extended to the professional component, or the interpretation, of diagnostic tests. In addition, the scope of what are considered purchased tests subject to the anti-markup rule has been greatly expanded. Where a physician or group bills for diagnostic tests performed by the physician or a member of the group, the anti-markup rule will apply if (i) the test or interpretation is purchased from an outside supplier or (ii) the test or interpretation is performed at a site other than the office of the billing physician or group. An outside supplier is someone who is not an employee of the physician or group, and does not furnish the test or interpretation under a reassignment of the right to bill Medicare to the billing physician or group. (Only persons who

are themselves Medicare providers can reassign the right to bill Medicare, which would include physicians but would not include technicians who perform the technical component of tests.) The office of a physician or group is restrictively defined as space where the physician or group regularly furnishes patient care and provides the full range of its services.

These new rules will likely prohibit many physicians and medical groups currently providing diagnostic tests and interpretations in space other than the offices where they see patients from marking up those tests or interpretations when Medicare is billed. In particular, many existing arrangements have been structured to comply with an exception under the federal self-referral law, known as the Stark law, for in-office ancillary services. That exception permits members of physician groups to order certain diagnostic tests from their groups, which would otherwise be prohibited by the Stark law, if, among other requirements they are rendered in a centralized building or the same building. Neither of these tests require that the services be rendered in the same office where the group provides patient care. In fact, in the case of a centralized building the billing group renders no patient care or services at all in the building.

As a consequence of these changes, the physicians or groups providing the diagnostic services may not be permitted to make any profit from their tests or interpretations when performed for Medicare patients, even though the arrangements fully comply with the Stark law.

The new regulations also make a number of changes with regard to IDTFs. The most significant of those changes concerns the shared use of IDTF facilities. New IDTF performance standards now prohibit any Medicare-participating IDTF from sharing its practice location or its diagnostic equipment with another Medicare-enrolled person or entity, or from subleasing its operations or its location to such person or entity.

This new rule clearly will prohibit timeshare arrangements, which have become increasingly popular in recent years, under which an IDTF leases space, equipment and staff on a part-time basis to a medical group, which then uses the facilities to provide Medicare-covered diagnostic services that are then billed by the medical group.

Because this new restriction is expected to greatly impact existing arrangements of many IDTFs, CMS is providing a one year transition period, meaning for existing Medicare-participating IDTFs the restriction will not become effective under January 1, 2009. For entities enrolling on or after January 1, 2008, the rule is effective immediately. CMS has exempted hospital-based and mobile IDTFs from this regulation.

ABOUT THE AUTHOR(S):

Hooper, Lundy & Bookman is the largest full service law practice in the country dedicated solely to the representation of health care providers. With offices in Los Angeles, San Francisco and San Diego, and clients in

46 states, Hooper Lundy & Bookman meets the business, litigation and regulatory needs of a broad array of health care providers--ranging from the largest national health care organizations to community hospitals and individual physician practices.

Robert W. Lundy, Jr. graduated with high honors from Yale University in 1972. In 1975, he received his J.D from the University of California at Los Angeles, where he was the recipient of the Distinguished Advocate Award.

Since 1978, Mr. Lundy has specialized in health care business transactions, including joint ventures, private placements, structuring of physician organizations, financing, acquisitions, mergers, alternative delivery systems, and licensing and certification matters. In 1987, together with Patric Hooper and Lloyd Bookman, formed the national health care law firm of Hooper, Lundy & Bookman in Los Angeles. As a founding member of Hooper, Lundy & Bookman, Inc., Mr. Lundy has continued to represent health care providers in a wide variety of business transactions.

Mr. Lundy was named one of Southern Californias Super Lawyers by L.A. Magazine for 2004, 2005, 2006 and

2007, was recognized in 2005, 2006, and 2007 by Chambers USA as one of the top health care lawyers in California and was nationally recognized as one of the Outstanding Healthcare Transaction Lawyers of 2003 by Nightingales Healthcare News. Mr. Lundy is the General Editor of LexisNexis/Matthew Benders five volume publication entitled Treatise on Health Care Law.

Analysis of California Prescription Drug Discount Program

2008 Emerging Issues 1711

Analysis of California Prescription Drug Discount Program

By Robert W. Lundy Jr.

December 28, 2007

SUMMARY: Hooper, Lundy & Bookman on California's Prescription Drug Discount Program. The California Prescription Drug Discount Program (Program) is designed to save Californians without health care coverage millions of dollars on the cost of prescription drugs. The discount program ostensibly is voluntary for drug manufacturers, but, beginning in 2010, there will be significant disadvantages to those manufacturers who do not offer discounts to the State of California under the Program. This commentary analyzes the statute and its impact in California.

PDF LINK: Click Here for Enhanced PDF of Commentary

ARTICLE: The California Prescription Drug Discount Program (Program) is designed to save Californians without health care coverage millions of dollars on the cost of prescription drugs. *See* Cal Health & Safety Code §§ 130500 et seq. As discussed below, the discount program ostensibly is voluntary for drug manufacturers, but, beginning in 2010, there will be significant disadvantages to those manufacturers who do not offer discounts to the State of California under the Program. In particular, those manufacturers that decline to participate in the Program could face the prospect of losing business from Californias Medicaid program, known as Medi-Cal. The details of the new drug discount program are set forth below.

Under the Program, certain eligible Californians, including those without prescription drug coverage and who also are under 300 percent of the federal poverty level, seniors, and those with high health care costs, receive a prescription drug card in exchange for a nominal $10 fee. The Program participants are able to present the discount cards at certain pharmacies under contract with the State of California and pay for designated drugs at lower prices negotiated between the State and particular drug manufacturers.

As mentioned, DHS is the agency responsible for negotiating with drug manufacturers for discounted prices on prescription drugs. Under express statutory terms, DHS is directed to attempt to negotiate with manufacturers to obtain discounts that are at or below certain benchmark prices, such as (1) eighty-five percent of the average manufacturer price for a drug, as published by the Centers for Medicare & Medicaid Services (CMS); (2) the lowest price provided to any non-public entity for a drug by a manufacturer and (3) the Medicaid best price. In order to facilitate the negotiating process, drug manufacturers may be required to furnish certain pricing information about their drugs to DHS.

The Program ostensibly is voluntary for drug manufacturers, as manufacturers are not required to offer discounts to

DHS. However, after the third year of the Program, there will be accountability for those manufacturers that have elected not to extend discounts to the Department. By statute, DHS is directed to evaluate whether the Program has been successful in ensuring that uninsured Californians have access to a formulary of drugs commensurate with the drugs available under the Medi-Cal program and at appropriately discounted prices. In connection with its assessment of the Program, beginning in 2010, the Department is authorized to require prior authorization in the Medi-Cal program for any drug if the manufacturer of the drug either has (1) failed to negotiate at all with DHS regarding drug discounts as part of the Program or (2) has failed to agree upon an appropriately discounted price for a particular drug under the Program.

Through the use of this prior authorization mechanism, the Department will be able to, in effect, steer Medi-Cal business away from manufacturers that elect not to participate in the Program and toward drug companies that do offer good discounts. In light of the fact that the Med-Cal program now spends approximately $4 billion a year on prescription drugs, the loss of Medi-Cal business could have a significant financial impact on many drug companies. In addition, the Department will be able to post on its website the names of drug manufacturers who do not enter into discount agreements under the Program, which could have a negative public relations impact on the listed drug manufacturers.

By the express terms of the relevant statutes, the Program became effective on January 1, 2007. However, we have spoken to someone at the Department who is responsible for the Program and have been informed that the Departments goal is to begin enrolling participants in the Program by the Summer of 2008. The Departments current implementation strategy is to have contracts in place with the drug manufacturers before it starts enrolling participants into the Program.

Given the stakes involved, drug manufacturers will want to negotiate aggressively with the Department to offer a discounted rate that is as favorable to them as possible. It likely will benefit manufacturers to use competent legal counsel in the negotiating process with DHS.

ABOUT THE AUTHOR(S):

Robert W. Lundy, Jr., is a founding partner of the national health care law firm of Hooper, Lundy & Bookman. Since 1978, Mr. Lundy has specialized in health care business transactions, including joint ventures, private placements, structuring of physician organizations, financing, acquisitions, mergers, alternative delivery systems, and licensing and certification matters. In 1987, together with Patric Hooper and Lloyd Bookman, he formed Hooper, Lundy & Bookman in Los Angeles. As a founding member of Hooper, Lundy & Bookman, Inc., Mr. Lundy has continued to represent health care providers in a wide variety of business transactions.

Mr. Lundy was named one of Southern Californias Super Lawyers by L.A. Magazine for 2004, 2005, 2006 and 2007, was recognized in 2005, 2006, and 2007 by Chambers USA as one of the top health care lawyers in California and was nationally recognized as one of the Outstanding Healthcare Transaction Lawyers of 2003 by Nightingales Healthcare News. Mr. Lundy is the General Editor of LexisNexis/Matthew Benders five volume publication entitled Treatise on Health Care Law. Mr. Lundy graduated with high honors from Yale University in 1972. In 1975, he received his JD from the University of California at Los Angeles, where he was the recipient of the Distinguished Advocate Award.