COA Report

A publication of the California Orthopaedic Association

Spring, 2012

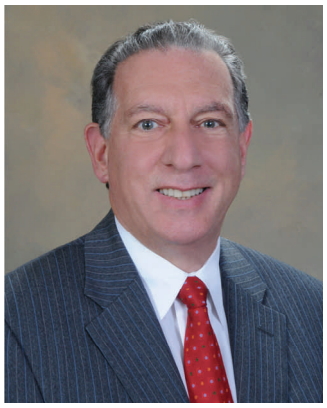
PRESIDENT MESSAGE

Dear Orthopaedic Colleagues

COA's 2012 Annual Meeting/QME Course is rapidly approaching. If you have not already registered to attend, please do so as soon as possible, so that you and your practice manager, can be updated on trends and strategies affecting your practice. Register online at: www.coa.org

The Annual Meeting /QME Course is April 19 – 22, 2012 at the Park Hyatt Aviara Resort, in Carlsbad, CA. This hotel was formerly a Four Season Resort with spectacular ocean views. It's a relaxing setting for our meeting.

Our Program Chairman Nick Abidi has organized an excellent agenda that will update you on the latest **clinical research** in all orthopaedic disciplines, provide a **hands-on cadaver lab in MSK injections under ultrasound**, and give you access to the state of the art **mobile surgical labs**. In addition, Bob O'Hollaren, is again bringing together leading orthopaedic consultants who can update you on **practice management strategies** to help your practice be successful.



Tye Ouzounian, M.D., President

A **coding session** on Thursday will update you and your staff on the correct way to code your procedures to ensure you are receiving the maximum reimbursement.

The sessions should be pertinent to orthopaedic surgeons in all types of practices. If you have not registered for the meeting, I would encourage you to review the program and consider attending along with your practice manager.

I have recently returned from the American Academy of Orthopaedic Surgeons' Annual Meeting in San Francisco. In conjunction with that meeting, your California Orthopaedic Association Board of Directors met to discuss and coordinate ongoing interests relevant to practice in California. We discussed mat-

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Highlights—COA Annual Meeting/QME Course

- Presidential Guest Speakers
- Advanced Ultrasound Course/Cadaver Lab
- Orthopaedic Practice Management
- QME Course
- AAOS Specialty Day Review

Register by March 1
to save up to $100—
Registration Fees.

On-Line Registration:
www.coa.org

President's Column (continued from Page 1)

ters unique to the practice of orthopaedic surgery in our state. Currently, our Board of Directors is well balanced with representatives from small private practices, large orthopaedic groups, multi-specialty groups, employed physicians, academic settings, and Kaiser Permanente. For many years, COA has provided current educational sessions that are unique to the practice of orthopaedics in California. Our state has historically experienced changes that are not present in other regions of the country. This continues to occur, at an increasingly rapid rate of change. Many of the changes are unique to individual local communities and may involve local contract issues as we have recently experienced with the CalPERS policy for their beneficiaries who have either Blue Cross PPO or Blue Shield HMO coverage on elective hip and knee replacement surgery. As some of you are aware, for those beneficiaries, CalPERS is only providing coverage for elective hip and knee joint replacement surgeries if they are performed in one of their "preferred facilities" or in a hospital that has agreed to a certain reimbursement level for the hospital facility fees. COA's Board will be reviewing this policy to see how we can preserve patients' access to these surgeries in their local communities. Providing information and explaining the options for those in practice on these and other issues affecting your practice will remain a high priority.

As more of us become involved in newer practice models and practice settings, COA's historical priorities may not be relevant to many of our members. We need your help to let us know how COA can be most relevant to you. We have also been actively working to expand COA's focus, so that we are addressing issues, we believe are relevant to members in these new practice models. Through the combined efforts of our Board, individual members and our committees, several new products have been developed this year that are not available elsewhere and are relevant to all orthopaedic surgeons.

ABOS Maintenance of Certification is a process that eventually all orthopaedic surgeons will need to participate in. We have improved our prior study flashcards and the flashcards are now also available as a smart phone study aid. The flashcards are available for all orthopaedic surgeons and orthopaedic residents preparing for their MOC. COA members receive a significant discounted price as a member benefit.

Timely information is powerful as we position our practices for the future, in this rapidly changing environment. COA is expanding its communication tools with our members. Our new publication, ***"Cal Ortho On-Line"*** provides timely, accurate practice information allowing you to make informed practice management decisions. This publication is reserved exclusively for COA members. These and other projects will be of value to diverse groups of orthopaedic surgeons.

Please feel free to contact me directly at: ouzouniant@aol.com, or through the COA office—coa1@pacbell.net.
Warmest regards,

Tye Ouzounian, MD, President

COA ORTHOPAEDIC CODING COURSE

Who should attend: Orthopaedic surgeons
Orthopaedic billing staff

When: Thursday, April 19, 2012
Held at COA's 2012 Annual Meeting Meeting
Park Hyatt Aviara Resort, Carlsbad (N. San Diego County)

Register on-line: www.coa.org

Stephanie Ellis, R.N.,CPC of Ellis Medical Consulting will present an orthopaedic coding course covering coding for:

- Knee Surgery—open and scope procedures
- Shoulder Surgery—open and scope procedures
- Foot and Ankle Surgery—open and scope procedures
- Hand & Wrist Procedures
- Issues Related to CCI Unbundling Edits related to orthopaedic coding
- Evaluation and Management
- Physician Extenders—physician assistant/nurse practitioner
- Coding Changes under ICD-10

In medical consulting for over 20 years, Stephanie specializes in orthopaedic coding and she has also worked as a fraud investigator for Medicaid. This course will be informative for coders of all levels.

Attendees will receive a comprehensive **orthopaedic coding manual**. You will also receive a summary of the following 2012 orthopaedic coding changes:

Highlights of 2012 Orthopaedic Coding Changes

- Evaluation and Management codes now include the terms "specialties" and "subspecialties," but the terms are not defined.
- Arthroscopy Codes—major changes on the bundling of services
- New Combination Codes—Spinal Fusion
- Guideline Changes to CPT 22552 and 22525
- Guideline Changes to Removal of Instrumentation
- Diskectomy Update—CPT Codes 63020, 63030, and 63035
- Injections—Reinforce that diagnostic/therapeutic injections are not separately reportable with CPT Codes 64600-64681
- Same Session EMG and NCS—New Add-on Codes 95885, 95886, and 95887
- Wound Repair
- New codes—Dupuytren's Contracture—20527 and 26341
- Infusion Pumps
- Modifier 33—Preventive Services
- Skin Replacement Surgery

Register today to take advantage of the reduced registration rates.

Hooper, Lundy, and Bookman HEALTH LAW E-ALERT

JANUARY 31, 2012

Drugs and Devices added to California Workers' Compensation Self-Referral Law: Does this Impact Physician-Owned Device Companies?

Effective January 1, 2012, California's workers' compensation self-referral law was expanded to apply to pharmacy goods, defined to include any dangerous drug or device. As a result, implantable medical devices requiring a physician's order, are now covered by the law, and questions have arisen regarding the impact this might have on physician owners of a medical device company who perform surgeries on California workers' compensation patients.

When enacting this change in the law, the Legislature made clear that it intended to address arrangements in which physicians provide prescription medical foods for their patients. There is no indication the Legislature gave any consideration to physician-owned device companies. Nevertheless, as amended, the law would now prohibit a physician from referring a patient for implants to a company that the physician owns or has a financial relationship with, unless an exception were available.

However, it does not appear that patients would be viewed as being "referred" to a medical device distributor, within the meaning of California's self-referral law. Therefore, ***this law does not appear to have any impact on physician-owned device companies***. Although the term "referral" is not defined in the statute, the California Attorney General, for many years, has relied on the standard dictionary definition of a referral for purposes of California's closely related anti-kickback statute as follows:

> The verb 'refer' is defined as 'to send or direct for treatment, aid, information, decision' (Webster's Third New Internat. Dict. (1971 ed.) at p. 1907, def. (2a)) and a 'referral' as 'the process of directing. . . a patient . . . to an appropriate specialist or agency for definitive treatment' (id., at p. 1908, def (1b)). The phrase 'referral of patients' . . . may thus be thought of as the process whereby a third party independent entity who initially has contact with a person in need of health care first selects a professional to render the same and then in turn places the prospective patient in contact with that professional for the receipt of treatment. (65 Ops.Cal.Atty.Gen. 252, 254 (1982).)

Accordingly, instead of the physician referring a patient to device distributor, the physician is referring the patient to a hospital or surgery center, and the hospital (or surgery center), upon the physician's order, purchases the implant from the distributor. The patient's relationship is with the hospital or surgery center where the patient receives care. There is no financial relationship or physical encounter between the patient and the distributor, and the distributor has no direct relationship with the patient. Under these circumstances, although the distributor sells an implant to the hospital upon a physician's order, we do not believe that there would be any prohibited referral of a patient to distributor by its physician owners.

There would, however, still need to be an exception allowing the physician to refer the patient to the hospital (because, through the distributor, the physician would have an indirect financial relationship with the hospital). However, as before, the law contains an exception allowing a physician to refer a patient to a hospital, so long as the physician is not paid for that patient referral (and any equipment lease between the parties meets certain requirements). This exception would continue to apply. For ambulatory surgery centers, the analysis is the same, because a similar exception applies for these referrals.

For additional information, please contact Charles Oppenheim, Bradley Tully, David Hatch, Karl Schmitz, or Eugene Ngai in Los Angeles at 310.551.8111; or Stephen Phillips in San Francisco at 415.875.8500.

News of Interest

California hospital, docs plan ACO with Blue Shield

Modern Healthcare is reporting that Hoag Memorial Hospital Presbyterian, Newport Beach, Calif., and Greater Newport Physicians have agreed to form an accountable care organization with Blue Shield of California. The three-year accountable care agreement must be approved by the California Department of Managed Health Care. Healthcare costs for roughly 11,000 managed care enrollees will remain largely flat during the first year which will begin July 1, to be followed by "low single-digit increases," according to the Blue Shield press release. The participating groups will share clinical and case management information as part of an effort to coordinate comprehensive healthcare services.

AMA Calls on Congress to Block ICD-10 Mandate on Doctors

Citing high implementation costs and coinciding federal mandates, the American Medical Association has urged House Speaker John Boehner to stop the switch to the new diagnosis coding sets known as ICD-10. AMA Executive Vice President and CEO James Madara, M.D. said in a letter to Boehner that requiring all physician practices to use new diagnosis codes as of October 1, 2013, will interfere with concurrent efforts by doctors to implement electronic medical records and satisfy other Medicare quality improvement requirements. ICD-10 contains about 68,000 codes while the current ICD-9 standard has only about 13,000 codes. The AMA says that the switch to ICD-10 represents a significant administrative burden, as the costs of implementing ICD-10 could range from $83,000 to $2.7 million depending on the size of the physician practices. Health technology industry groups have defended the push to ICD-10. They say that implementation will not be as expensive as some have estimated and would allow physicians to capture more precise data that they can use in their payor negotiations.

Medicare E-Prescribing Exemption

Physicians are complaining that even though they filed a "hardship exemption" with the Centers for Medicare and Medicaid (CMS) to be exempted from their minimum E-Prescribing requirement to avoid the 1% reduction in their fees as of January 1, 2012, their payments are still being reduced. This may be affecting orthopaedic practices as many practices prescribe narcotic medications and were unable to e-prescribe these medications to meet the minimum CMS E-Prescribing requirements.

Why is this happening?

It seems that CMS has been overwhelmed by the volume of hardship requests and they have not yet been able to review them in a timely manner. Therefore, the payment adjustment was applied to everyone who requested an exemption. Once CMS reviews the requests, those who qualify for the exemption will get a retro-correction to their reimbursement. If CMS determines that a provider submitted incorrect or incomplete information, then CMS will not grant the exemption. We are also hearing there may be a problem if a provider has multiple PTANs and more than one Tax ID number tied to the PTANS. Groups are required to request an exemption for all of the Tax ID numbers. Otherwise, you may receive an exemption for one Tax ID and not the others.

COA has contacted Palmetto to determine when CMS will be correcting the reimbursements but, to date we have not been given a timeline. We have, however, been told that CMS understands this is a problem and they are dedicating additional resources to the review the exemptions.

Issues with 5010 Implementation

Physicians nationwide are reporting problems with the 5010 implementation. The AMA is acutely aware of the cash flow issues surrounding claim rejections related to this transition and urges physicians and their practice staff to work closely with their billing services or clearinghouses to help resolve them. COA has learned that on February 9, 2012 some of the transmission problems were resolved allowing many claims to make it through the process. Even though providers are receiving confirmation that their claims have been transmitted, there also seems to be a delay in them showing up in your on-line account indicating that they are awaiting payment.

If you are a physician who is experiencing claims/cash flow interruptions with Medicare and have been unable to resolve your issues by contacting Palmetto GBA, you may complete the AMA's complaint form, which they will forward on to Medicare for resolution.
Physicians who are experiencing trouble with commercial or other payers may use their "click and complain" process.

CMS Requires new ABN Form for 2012

The Centers for Medicare and Medicaid Services (CMS) has revised the Advanced Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131. This form is used by health care providers, including physicians, when they expect Medicare will deny payment. The revised form replaces ABN-G (Form CMS-R-131G), ABN-L (Form CMS-R-131L), and NEMB (Form CMS-20007).

The latest version of the ABN (with the release date of 3/2011 printed in the lower left hand corner) is now available for immediate use and can be accessed via the link below.

Use of the revised ABN form will be mandatory starting January 1, 2012.

This date was extended from September of 2011 to January of 2012 to accommodate those with pre-printed stockpiles of ABNs. All ABNs with the release date of 3/2008 that are issued on or after January 1, 2012 will be considered invalid. Visit the CMS website for copies of the revised form and more information.

Kudos to COA Members

"Our Hearts to Your Soles"

Last fall, nearly 200 people, mostly homeless, lined up outside the Santa Cruz Homeless Shelter waiting for a free medical foot inspection and a new pair of donated leather work boots—boots that can spell the difference between a winter of pain and serious injury, or comfort and opportunity.

"Our Hearts to Your Soles" was held in 25 cities around the country in 2011. The event was sponsored in Santa Cruz by the Santa Cruz Orthopedic Institute where COA Member, Dr. Nicholas Abidi practices. The non-profit campaign was founded in 2004 by orthopaedic surgeon Stephen Conti from Pittsburgh.

Dr. Abidi and his wife, Dr. Beth Abidi, participated in this effort by examining their feet, checking for diabetes or any infection, and fitting participants with a pair of comfortable boots, manufactured and donated by Red Wing and P.W. Minor shoes.

Dr. Abidi indicated that it's important to be part of this program "since the homeless tend to be on their fee a good portion of the day, so when it's raining out and their shoes don't fit and they don't have dry socks, they end up in hospitals needing treatment for serious conditions."

Kudos to Drs. Nick and Beth Abidi for their outreach to their community.

"Operation Walk USA"

In 2011, over 80 patients throughout the United States received a free joint replacement as a result of orthopaedic surgeons participating in the "Operation Walk USA" program. "Operation Walk, USA," a non-profit organization of volunteer surgeons, has been created to provide pro bono surgical treatments to uninsured, underinsured, or poverty-stricken patients in the United States suffering from disabiling arthritis and other debilitating bone and joint conditions. It takes the cooperation and donation of time of the surgeons, their local hospitals, device manufacturers, and rehab specialists to make these surgeries possible.

COA Members, Larry Dorr, M.D., William Long, M.D., and Paul Gilbert, M.D. participated in the 7 surgeries performed at Good Samaritan Hospital in Los Angeles in 2011.

Kudos to Dr. Dorr and his team. If you would like to get involved in "Operation Walk USA" in 2012, please contact the COA office for more information—916-454-9884.

AMA Practice Alert

What you need to know about new, emerging physician payment models

Budget-based payment systems are beginning to augment or even replace the fee-for-service payment model.

The American Medical Association (AMA) wants to make sure your practice is equipped with nuts and bolts information about these new payment models. The AMA has developed a new "how-to" manual to help your practice evaluate, negotiate, and manage budget-based payment systems, including payment bundling, pay-for-performance, withholds and risk pools, capitation and shared savings.

"**Evaluating and negotiating emerging payment options**" provides you with practical information and tools to help you assess the financial impact of a new payment model, negotiate precise terms of the arrangement and manage changes to your revenue cycle.

Prepare your practice to succeed under new, emerging payment systems.

Visit www.ama-assn.org/go/payment today to learn how to make these budget-based payment systems work for your practice.

Receive a copy of the AMA "Evaluating and Negotiating Emerging Payment Options" at COA's 2012 Annual Meeting.

Medicare News

Hooper Lundy Bookman

By: Nina N. Adatia

New Medicare Accreditation Requirement Effective January 1, 2012

Beginning January 1, 2012, suppliers who bill Medicare for the technical component of advanced diagnostic imaging ("ADI") procedures must be accredited by an approved national accrediting organization to receive reimbursement for those services. Suppliers who are not accredited by January 1, 2012, and who attempt to bill Medicare for the technical component of ADI services after that date, will not be reimbursed for those services until they become accredited.

The accreditation requirement only applies to suppliers paid under the Physician Fee Schedule. Suppliers include, but are not limited to, physicians and non-physician practitioners, including clinics, and independent diagnostic testing facilities ("IDTF"). For purposes of this requirement, "advanced diagnostic imaging procedures" is defined to include diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine imaging, such as positron emission tomography. X-ray, ultrasound, and fluoroscopy procedures, as well as diagnostic and screening mammography, are expressly excluded from the accreditation requirement.

Accreditation is granted to the suppliers of the images themselves and not to the physicians interpreting the images, and these suppliers must be accredited for each ADI modality for which they intend to bill. Some of the basic areas that are reviewed for accreditation include personnel qualifications for non-physician medical staff, medical directors, and supervising physicians, image quality, equipment performance, safety standards for staff and patients, and quality assurance and quality control.

Currently, the Centers for Medicare and Medicaid Services ("CMS") has approved three national accrediting organizations, the American College of Radiology, the Intersocietal Accreditation Commission, and the Joint Commission, to grant accreditation to suppliers of ADI services. The specific quality standards, accreditation cycle, accreditation process and prices differ among these organizations, so suppliers should contact each of the three designated organizations to determine which meets their specific business model and philosophy for patient care.

If an enrolled supplier does not become properly accredited until after January 1, 2012, that supplier will only be reimbursed by Medicare for the technical component of ADI services as of the effective date of the accreditation. Thus, suppliers who are not yet accredited should begin the accreditation process right away to ensure that they are properly accredited by the deadline. Though processing times vary depending on the accrediting organization and the complexity of the supplier organization, the accreditation process is currently estimated to take approximately four to five months upon receipt of a complete application. Suppliers that are already accredited by one of the approved organizations should ensure that any renewal materials that are due this year are properly submitted so that their accreditation continues to be effective and they are in good standing on January 1, 2012.

Once an existing supplier receives the appropriate accreditation, the supplier need not inform CMS of its accreditation. Instead, the supplier's accrediting organization will transmit the findings of its accreditation decision, including identifying information, the accreditation effective date, and the modalities that are included in the accreditation, to CMS or its contractor when those decisions become final.

Suppliers who are not yet enrolled in Medicare but intend to enroll and bill for ADI services should also prepare to satisfy this accreditation requirement. Of note, CMS has recently revised its 855 enrollment applications to allow suppliers to list their ADI accreditation information on the applications themselves.

CMS has posted basic information about the accreditation requirement and various resource materials, including direct links to the approved accrediting organizations' websites, at https://www.cms.gov/MedicareProviderSupEnroll/03_AdvancedDiagnosticImagingAccreditation.asp.

Hooper Lundy Bookman
HLB HEALTH LAW E-ALERT
FEBRUARY 21, 2012

"60-Day Rule" Proposed Regulations Would Create Intense Time Pressure for Providers to Report and Return

I. Introduction

On February 16, 2012, CMS published in the Federal Register its much-anticipated (and long-awaited) notice of proposed rule making (NPRM) regarding Medicare provider and supplier[1] obligations to report and return overpayments (Proposed Rule). [2] The Proposed Rule would implement Section 6402(a) of the Affordable Care Act (ACA),[3] also known as the "60-day rule," which requires providers, suppliers, Medicare Advantage organizations, prescription drug plan sponsors, and Medicaid managed care organizations to report and return an "overpayment" within the later of (a) 60 days after the overpayment is "identified," or (b) the date any corresponding cost report is due, if applicable. Section 6402(a) defines an "overpayment" as any funds a person receives or retains under Medicare or Medicaid to which the person, after "applicable reconciliation," is not entitled. The 60-day rule applies not only to common claims-related overpayments, such as duplicate billings, but also to claims submitted pursuant to referrals made in violation of the federal Stark and anti-kickback laws. Any overpayment retained after the deadline for reporting and returning an overpayment constitutes an "obligation" for purposes of the federal civil False Claims Act (FCA). A related provision under the ACA also subjects providers who fail to comply with the 60-day rule to potential Medicare and Medicaid exclusion and civil monetary penalties under the federal Civil Monetary Penalty (CMP) statute.

Since its enactment nearly two years ago, the "60-day rule" statute has been a nightmare for providers and their counsel because it contains the toxic mix of vague terms and potentially disastrous consequences for noncompliance. For example, it fails to define several critical concepts, including when an overpayment is "identified" (*i.e.*, when the 60-day clock starts ticking), what constitutes an "applicable reconciliation" process that could delay the "report and return" period (*i.e.*, whether such a process is limited to cost report reconciliation), whether administrative finality under Medicare's reopening regulations affects the definition of an overpayment, the effect of the CMS and Office of Inspector General (OIG) self-disclosure protocols on the 60-day reporting deadline and, while not an ambiguity in the statutory terms, whether and to what extent CMS will apply the 60-day rule to overpayments that predate the effective date of ACA and whether such retrospective application depends on whether the overpayment is discovered before or after the effective date of ACA.

While the Proposed Rule, if finalized, would inject some additional certainty into the 60-day rule, it would do so in a manner that would be burdensome for providers, would put providers under intense time and cost pressure, and would do some violence to already settled expectations under the current regulatory scheme. CMS appears to be starting from a position dictated by Department of Justice litigation positions advocated in false claims actions - *e.g.*, defining "identification" as consisting of knowledge of the fact of an overpayment and subjecting providers to a 10-year lookback period in identifying certain claims-based overpayments - and using the 60-day rulemaking comment period to offer the provider community an opportunity to convince CMS why it should apply a less stringent approach. The provider community should seize this opportunity to so comment. The Proposed Rule is also notably silent on important issues, such as how providers should handle a situation where the provider cannot quantify the amount of an overpayment within 60 days; whether providers can use the existing Medicare adjustment bill process to resolve overpayments resulting from claims that are within the 12-month claims correction window; and how CMS will address potential retroactive enforcement issues created by the 10-year lookback period.

This Alert highlights the requirements the Proposed Rule would impose and discusses some of the key legal, operational, and technical issues the Proposed Rule raises and on which providers may want to submit comments.

II. Overview of the Proposed Rule

All Medicare Part A and Part B Providers Affected. The Proposed Rule would implement the 60-day rule only with respect to providers of Medicare Parts A and B items and services. CMS has indicated that it will address the other "persons" subject to the 60-day rule (*i.e.*, Medicaid managed care organizations, Medicare Advantage organizations, and Medicare Part D Plan sponsors) at a later date. However, CMS notes in the preamble to the Proposed Rule (Preamble) that even in the absence of a final regulation, all stakeholders subject to the 60-day rule could face potential FCA and/or CMP liability under existing statutory provisions.

Definitions. The Proposed Rule provides three express definitions - "Medicare contractor," "overpayment," and "person" - that are consistent with existing statutory and regulatory definitions. Other key concepts and terms are defined throughout the 60-day rule regulation itself. The Preamble provides several examples of "overpayments," including:

- Medicare payments for non-covered services
- Medicare payments in excess of the allowable amount for an identified covered service
- Errors and non-reimbursable expenditures in cost reports
- Duplicate payments

Receipt of Medicare payment when another payor had the primary responsibility for payment

Basic Rule. Under the Proposed Rule, if a person has "identified" that the person has received an overpayment, the person must report and return the overpayment by the later of (i) the date which is 60 days after the date on which the overpayment was identified, or (ii) the date any "corresponding cost report" is due, if applicable. Any overpayment retained by a person after the applicable deadline would become an "obligation" for purposes of the federal FCA.[4]

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60-Day Rule" Proposed Regulations

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"Identification" Defined Broadly to Include Knowledge of the Fact of an Overpayment. The Proposed Rule provides that a person has "identified" an overpayment if the person has "actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment." CMS acknowledges in the Preamble that in some cases, a provider may receive information concerning a potential overpayment that creates an obligation "to make a reasonable inquiry" to determine whether an overpayment exists; failure to make such an inquiry "with all deliberate speed" (perhaps as little as 60 days) could result in the provider knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received an overpayment. Once a potential overpayment has been confirmed, the provider would have 60 days to report and return it. The Preamble provides a non-exhaustive list of examples of when an overpayment has been "identified," including:

- A provider receives an anonymous compliance hotline complaint about a potential overpayment and fails to make a reasonable inquiry into the complaint
- A provider learns that a patient death occurred prior to the service date on a claim that has been submitted for payment
- A provider performs an internal audit and discovers that overpayments exist. A provider is informed by a government agency of an audit that discovered a potential overpayment, and the provider fails to make a reasonable inquiry

None of these examples distinguishes the "existence" of an overpayment from the ability of the provider to "quantify" the amount of the overpayment for purposes of the definition of "identification" under the statute. Thus, we are concerned that CMS views knowledge of an issue of overpayment as sufficient to begin the 60-day clock, without regard to how long it might reasonably take the provider to determine the correct amount of the overpayment.

"Applicable Reconciliation" Limited to Cost Reports. The Preamble confirms CMS's intent to limit "applicable reconciliation" to cost report reconciliation; i.e., in situations where CMS makes interim payments to a provider throughout the cost reporting year and the provider reconciles those payments with covered and reimbursable costs at the time the cost report is due. Accordingly, the Proposed Rule defines applicable reconciliation as occurring when a cost report is filed, except where the provider either receives updated SSI ratio information, or knows that an outlier reconciliation will be performed, in which cases the provider is not required to return any resulting overpayment until the final reconciliation of the applicable cost report. In addition, the Preamble states that providers may rely on the "applicable reconciliation" cost report deadline only in cases where cost report reconciliation would be relevant to the determination of whether an actual overpayment exists. For example, an overpayment related to graduate medical education (GME) payments must be reported and returned either 60 days after it has been identified or on the date the cost report is due, whichever is later. By contrast, issues involving upcoding must be reported and returned within 60 days of identification, because upcoded claims for payment are not submitted to Medicare in the form of cost reports.

Use of Existing Self-Disclosure Protocols (Mostly) Suspends 60-Day Deadline. In recognition of the interaction between the 60-day rule's obligation to report and return overpayments and existing procedures for providers to self-disclose actual or potential Stark violations to CMS through the Medicare Self-Referral Disclosure Protocol (SRDP), the Proposed Rule suspends the obligation to return overpayments under the 60-day rule when CMS acknowledges receipt of a disclosure made pursuant to the SRDP. Suspension of this obligation continues until CMS enters a settlement agreement with the person, the person withdraws from the SRDP, or the person is removed from the SRDP. However, the Preamble clarifies that SRDP disclosures do not suspend the obligation to report overpayments to the applicable payor. Similarly, CMS has proposed suspending the obligation to return overpayments under the 60-day rule when OIG acknowledges receipt of a submission to the OIG Self-Disclosure Protocol (SDP), which enables providers to self-disclose evidence of potential fraud to OIG. As with SRDP submissions, suspension of this obligation continues until OIG enters a settlement agreement with the person, the person withdraws from the SDP, or the person is removed from the SDP. Unlike SRDP submissions, however, the Proposed Rule characterizes a disclosure under the SDP as a report for purposes of the 60-day rule's reporting requirements (although the provider still must make the SDP disclosure in accordance of the 60-day rule's timeliness requirements), and so providers who receive OIG acknowledgment of receipt for SDP disclosures would not be required to make a separate report of the overpayment.

Overpayment Reports Rely on Existing Voluntary Refund Processes, But Must Contain Specified Elements. Under the Proposed Rule, a provider who identifies an overpayment must make a written report to the applicable payor that contains all of thirteen specified elements, including: (1) the person's name; (2) the person's tax identification number; (3) how the error was discovered; (4) the reason for the overpayment; (5) the health insurance claim number (as appropriate); (6) the date of service; (7) the Medicare claim control number (as appropriate); (8) Medicare National Provider Identification (NPI) number; (9) a description of the corrective action plan to ensure the error does not occur again; (10) whether the provider has a corporate integrity agreement with OIG or is under the OIG's SDP; (11) the timeframe and total amount of the refund for the period during which the problem existed that cause the refund; (12) if a statistical sample was used to determine the overpayment amount, a description of the statistically valid methodology used to determine the overpayment; and (13) a refund in the amount of the overpayment.

The Preamble notes that CMS intends to use the "existing voluntary refund process," which will be renamed the "self-reported overpayment refund process," to implement the 60-day rule. Under this process, CMS intends for providers to report overpayments using a form that Medicare contractors make available on their websites.[5] Accordingly, the Proposed Rule requires that except for persons who have satisfied the reporting requirement through making a disclosure under the OIG SDP and entering into a settlement agreement under the SDP, persons subject to the 60-day rule must use the self-reported overpayment refund process set forth by the applicable Medicare contractor to report and return overpay-

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60-Day Rule" Proposed Regulations

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ments.[6] Consistent with this approach, the Proposed Rule provides that a person may request an "extended repayment schedule" (ERS) when submitting an overpayment report, and that the ERS is "the only means by which extended repayment of an overpayment will be permitted." The Preamble notes that CMS included this provision in recognition of concerns over scenarios in which a provider has identified an overpayment, but because of the magnitude of the overpayment, needs additional time to make repayment. CMS cautions that providers may not delay the identification date in these scenarios, but rather must use the existing ERS process as outlined in the Medicare Financial Management Manual. In addition, the Preamble warns providers that requests for ERS "are not automatically granted," and that providers seeking to avail themselves of this process will be required to submit "significant documentation" to support a claim that timely repayment of the overpayment represents a "true financial hardship" for the provider.[7]

Ten-Year Lookback and Claims Reopening Periods. The Proposed Rule provides that an overpayment must be reported and returned if a person identifies the overpayment "within 10 years of the date the overpayment was received." The Preamble indicates that CMS chose a 10-year lookback period because this is the outer limit of the federal FCA statute of limitations, and believes this period is appropriate because providers and suppliers "should have certainty after a reasonable period that they can close their books and not have ongoing liability associated with an overpayment." In connection with the 10-year lookback period, the Proposed Rule amends the Medicare claims reopening rules to provide that overpayments reported under the 60-day rule implementing regulations may be reopened for a period of 10 years from the date of initial determination or redetermination. There is no corresponding proposed amendment to the notice of program reimbursement (NPR) determination regulatory reopening period, which remains three years. Thus, it seems to us that the lookback period for cost reporting issues remains at three years from an NPR, absent fraud or similar fault, which tolls the running of that three-year period.

CMS Estimates Low Compliance Burden. Finally, the Preamble estimates that approximately 8.5% of the total number of Medicare providers will report and return overpayments in a typical year under the Proposed Rule, and that each of these providers would report and return approximately three to five overpayments at a total time investment of 2.5 hours per overpayment to complete the applicable reporting form and return the overpayment. The Preamble notes that CMS assumes two categories of individuals will be involved in completing and submitting the applicable reporting form - accountants and auditors (both external and in-house), and "miscellaneous in-house administrative personnel." Based on these assumptions, CMS calculates a combined mean hourly wage of $37.10 per hour, for a total estimate compliance cost of approximately $92.75 per overpayment, or approximately $278.25 - $463.75 per provider per year. These estimates appear to be unrealistically low, given the complexity providers and their counsel frequently encounter investigating and analyzing whether there has been an overpayment, and then calculating the amount of the overpayment.

III. Challenges for Providers under the Proposed Rule

The Proposed Rule presents several significant operational, technical, and legal issues upon which providers may wish to comment.

"Identification" Standard Disregards Difficulties in Quantifying Amount of Overpayment. Perhaps the most significant "report and return" issue the Proposed Rule raises is the definition of "identification" as including actual knowledge, deliberate ignorance, or reckless disregard of the "existence of an overpayment," without regard to a provider's ability to quantify the amount of the overpayment. In a surprising omission, the Proposed Rule is wholly silent about how a provider should handle the situation where it knows that it has been overpaid, but cannot quantify the overpayment within 60 days (even with reasonable diligence). A provider's inability to quantify an overpayment within 60 days apparently would not diminish the provider's obligation to report and return it within that time-frame, even though CMS insists that one of the elements that the provider must include in the report is the "total amount of the refund."

As noted above, following the passage of the ACA and the "60-day rule" statute, the provider community was left to fend for itself in determining what it meant to "identify" an overpayment. In the absence of guidance from CMS, various views emerged regarding an "appropriate" interpretation of the 60-day rule. These views ranged from viewing any notice of the existence of a potential overpayment as constituting "identification" (the "whiff test"), to requiring actual knowledge of both the existence and full amount of the overpayment and the absence of any good-faith counter-arguments to the provider's entitlement to payment before an overpayment is "identified," to somewhere in between.

The Proposed Rule adopts an expansive approach to "identification" - essentially the "whiff test." Accordingly, the Proposed Rule would place significant pressure on a provider's internal reporting capabilities and ability to conduct relatively rapid investigations of any potential indication that an overpayment may have occurred. The use in the Proposed Rule of the federal FCA's actual knowledge/deliberate ignorance or reckless disregard standard, while not equivalent to a "knew or should have known" standard, raises the possibility that the government may come in behind a provider and second-guess whether a provider exercised "reasonable diligence" and made a "reasonable inquiry" "with all deliberate speed" in determining when an overpayment should have been identified.

If the Proposed Rule's definition of "identification" is finalized, providers will probably need to run their factual and legal processes concurrently following any initial credible suggestion of a potential overpayment and resolve the issue during the following 60 days. To the extent the investigation takes longer than 60 days, the provider would seem to be at some enforcement risk if an overpayment is ultimately found, although providers possibly could mitigate this risk through a compelling and documented basis for extending the investigation/resolution process past 60 days. The Proposed Rule is silent, however, regarding whether and to what extent CMS would accept an investigation that extends beyond 60 days. This time pressure, combined with serious consequences for non-compliance, may force providers to err on the side of disclos-

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ing potential overpayments, which could increase both the volume of overpayment reporting, as well as the time and cost associated with such reports, and could result in the return of funds that are ultimately found not to have been overpayments.

Proposed Rule Does Not Address Use of Claims Correction Processes. In another surprising omission, the Proposed Rule does not discuss whether providers can use Medicare's existing adjustment bill/claims correction processes to resolve overpayments resulting from claims that are identified within the one-year claims correction window, or whether providers must report and repay such overpayments using the regulatory process set forth in the Proposed Rule. Many providers have relied on Medicare's existing claims correction processes to adjust overpayments without resorting to the 60-day rule's report and refund provisions, and this approach has enabled quick and relatively inexpensive resolution of such overpayments. Given the Proposed Rule's ostensible goal of relying on existing processes in implementing the 60-day rule (*e.g.*, the voluntary refund and ERS request processes), it would be alarming if CMS precluded providers from utilizing existing Medicare claims correction processes to resolve overpayments where the claims are within the one-year resubmission window. Despite this conflict, the Proposed Rule provides no guidance on this issue, and so it is unclear whether CMS intends to prohibit providers from using the long-standing claims correction process under the 60-day rule implementing regulations.

10-Year Lookback Period Raises Retroactivity Issues. Finally, the Proposed Rule's expansive 10-year lookback period and corresponding amendments to the Medicare claims reopening regulation raise significant questions regarding retroactive application of the 60-day rule. For example, it is unclear whether the sanctions enacted under the ACA for failure to report and repay an overpayment within the 60-day rule's deadlines will apply to overpayments identified before March 23, 2010 (*i.e.*, the ACA's passage). Because these sanctions attached to retention of an identified overpayment beyond 60 days, CMS might interpret the 60-day rule to require all overpayments identified prior to March 23, 2010 to have been reported and repaid within 60 days of the ACA's passage (*i.e.*, under a "continuing violation" theory). However, such an interpretation would conflict with existing case law and arguably could conflict with Medicare's "without fault" rules. It is also unclear from the language of Section 6402(a) of the ACA where Congress provided CMS with the authority to extend retroactively the time limit under the Medicare reopening regulation from four to 10 years. Such retroactive application would violate the "settled expectations" test for permissible retroactivity. Finally, it seems an inequitable result for CMS to impose a 10-year lookback period for identifying overpayments without creating a parallel offset for identifying underpayments. In any event, the Proposed Rule is silent regarding the retroactive application of the 60-day rule and how CMS will interpret these significant legal issues.

IV. Conclusions and Next Steps for Providers

If the regulations implementing the 60-day rule are finalized as currently proposed, CMS's approach to interpreting the 60-day rule will create intense time pressure for providers and will significantly increase the operational, and potentially financial, burdens of overpayment disclosure.

The Proposed Rule's definition of "identification" as consisting of a provider's knowledge of the existence of an overpayment places significant emphasis on the strength of a provider's internal controls and compliance program, and the ability to move fast. Given the time constraints and serious penalties associated with the 60-day rule, providers would be well-served to review their internal overpayment identification and escalation processes to ensure that providers have the systems in place to quickly identify and analyze potential overpayments, including the engagement of experienced in-house and outside counsel as appropriate.

In addition, while the Proposed Rule provides a degree of additional clarity surrounding the application of the 60-day rule, the Proposed Rule is also notable in its silences - particularly with respect to the common and well-known issues surrounding difficulties in quantifying overpayments within 60 days and reliance on the existing Medicare claims correction process to address overpayments within the one-year resubmission window. We can only assume that CMS's silence constitutes an invitation for the provider community to offer comments and suggestions about how CMS might approach these issues - an invitation the provider community should enthusiastically accept.

Although the Proposed Rule is limited to Medicare Part A and Part B providers and suppliers, CMS likely will interpret and enforce the 60-day rule against all "persons" in a manner generally consistent with the Proposed Rule once it is finalized. Accordingly, all stakeholders subject to the 60-day rule have a vested interest in the shape the final regulations will take. Hopefully, CMS will be receptive to comments from the provider community regarding the Proposed Rule and will take them into account while providing further guidance and clarity in the final rule.

For additional information, please contact the following:
Los Angeles: Patric Hooper, John Hellow, Jon Neustad ter, Mark Hardiman at 310.551.8111
San Francisco: Mark Reagan, Paul Deeringer at 415.875.8500
Washington, DC: Robert Roth at 202.587.2590

[1] We use the term "provider" herein to refer to both Medicare providers and suppliers.
[2] 77 Fed. Reg. 9179-9187 (Feb. 16, 2012). Comments are due no later than 5:00 p.m. Eastern time on April 16, 2012.
[3] Section 6402(a) has been codified at 42 U.S.C. § 1320a-7k(d).
[4] As noted above, retention of an overpayment beyond the applicable 60-day rule deadline also may subject a provider to CMP liability and exclusion from Federal health care programs.
[5] *See*, *e.g.*, Palmetto GBA Medicare, Overpayment Refund Form: Medicare Part A and B, *at* http://www.palmettogba.com/Palmetto/Providers.Nsf/files/J1_overpayment_refund_form_revised.pdf/$File/J1_overpayment_refund_form_revised.pdf (last accessed Feb. 15, 2012).
[6] The Preamble recognizes that different Medicare contractors may have different forms, and notes that CMS plans to develop a uniform reporting form that will enable all overpayments to be reported and returned in a consistent manner.
[7] In connection with CMS's intent to permit use of ERS requests in the overpayment reporting process, the Proposed Rule amends the definition of "hardship" in the Medicare claims collection regulations to include overpayments reported under the 60-day rule implementing regulations.

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People in the News

Vernon Tolo, M.D., of Los Angeles received the William W. Tipton Jr., M.D. Leadership Award at the AAOS 2012 Annual Meeting in San Francisco.

Marilyn Tavenner has been appointed the new Acting CMS Administrator. Ms. Tavenner is a nurse and she has previously served in the Obama Administration as Medicare's Principal Deputy Administrator.

Michael Klassen, M.D. of Monterey has been elected Member-at-Large to the Executive Committee of the AAOS Board of Councilors**.**

Thomas Sampson, M.D. of San Francisco, has been elected President of the International Society for Hip Arthroplasty.

John Meehan, M.D. of Sacramento, is the recipient of the Winter 2011 Orthopaedic Research Education Foundation/ Current Concepts in Joint Replacement (OREF/CCJR) Clinical Practice Award.

Darryl D'Lima, M.D. of La Jolla is the recipient of the Association of Bone and Joint Surgeons (ABJS) Nicholas Andry Award. Co-authors included: **Clifford Colwell, Jr., M.D.** also of La Jolla.

Thank You to COA Members who contributed to COA's Political Action Committee (OPAC).

COA is fortunate that over 70% of its members have contributed to OPAC this year. Your support is very much appreciated.
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